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Flanders Medical Research Program

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Overview about technologies available to treat complex SFA / POP lesions

Dr. Marc Bosiers

CICE 2017, São Paulo

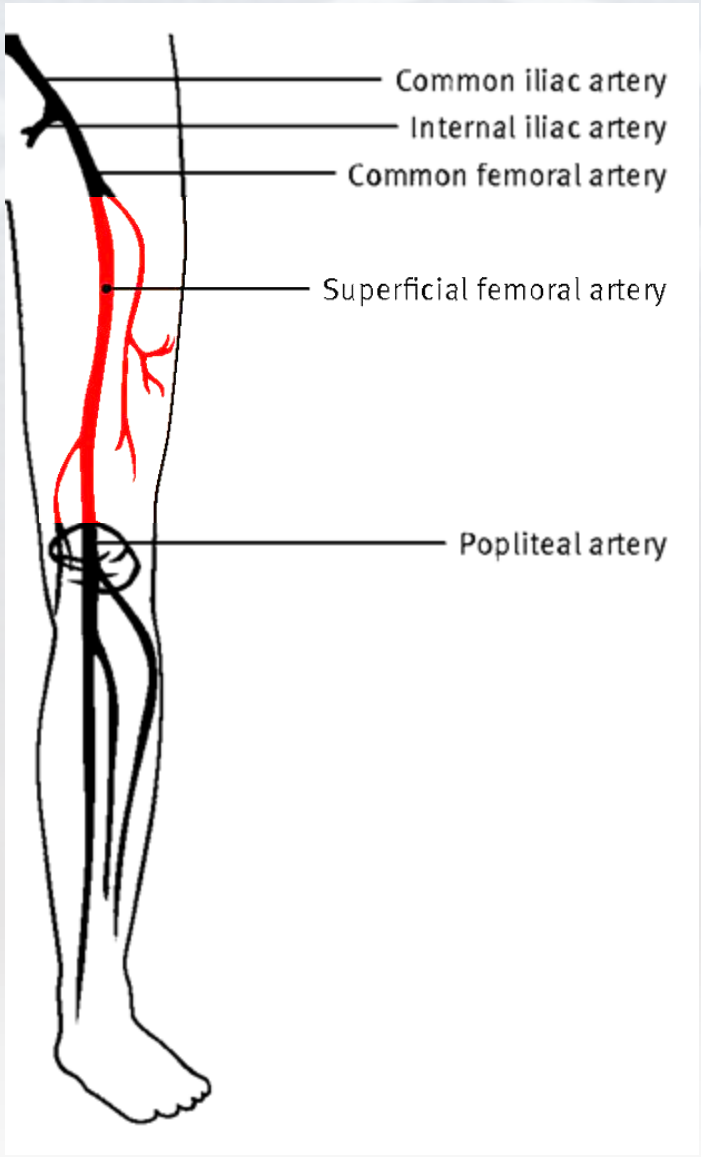
Conflict of interest

☐ have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☑ I do not have any potential conflict of interest

Superficial Femoral Artery



1. Femoropopliteal Artery

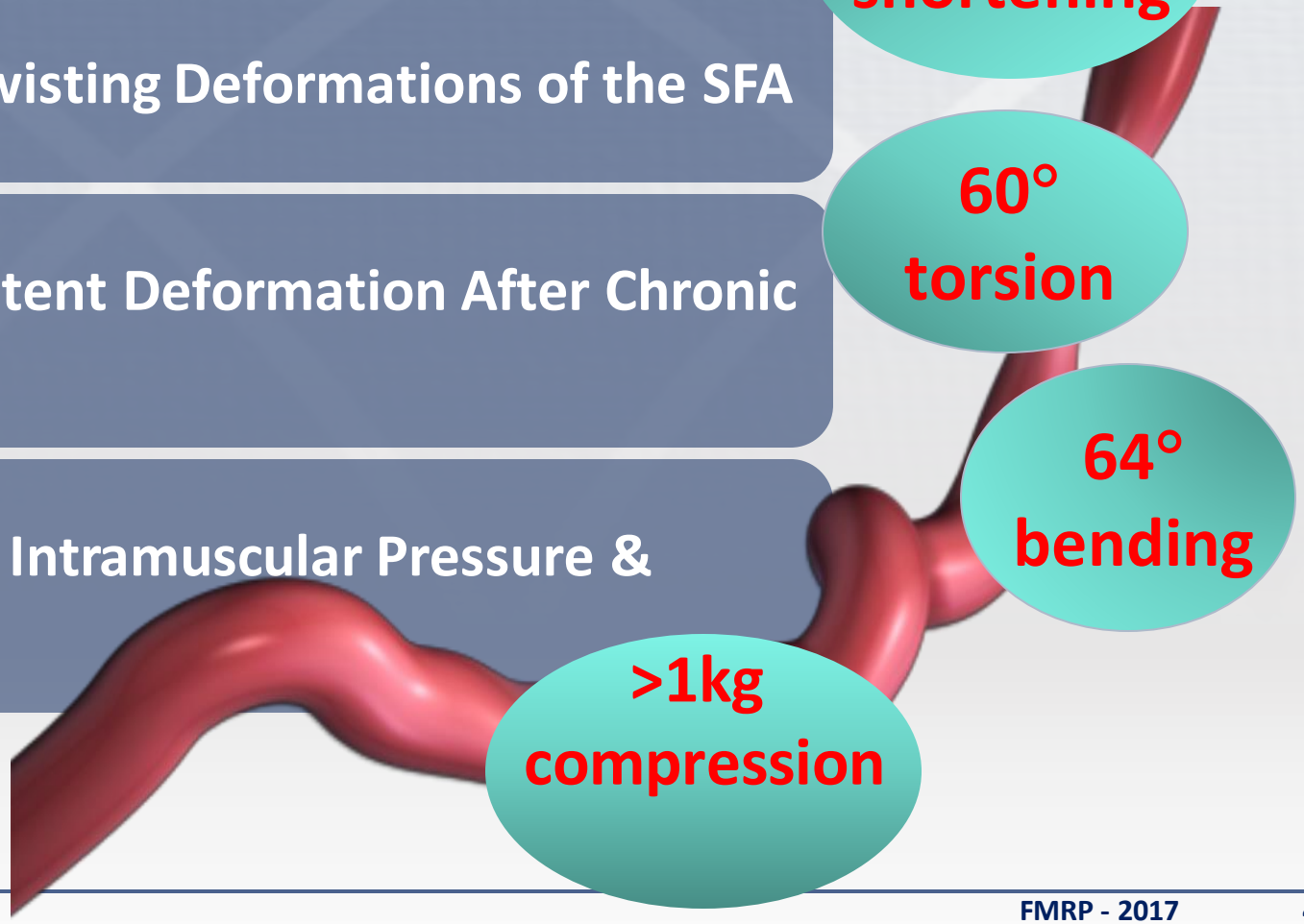
The SFA is a challenging vessel to treat

Jonker et al.,
Dynamic Forces in SFA During Knee Flexion
Endovascular Today. Buyer's Guide 2009, pp. 54–59

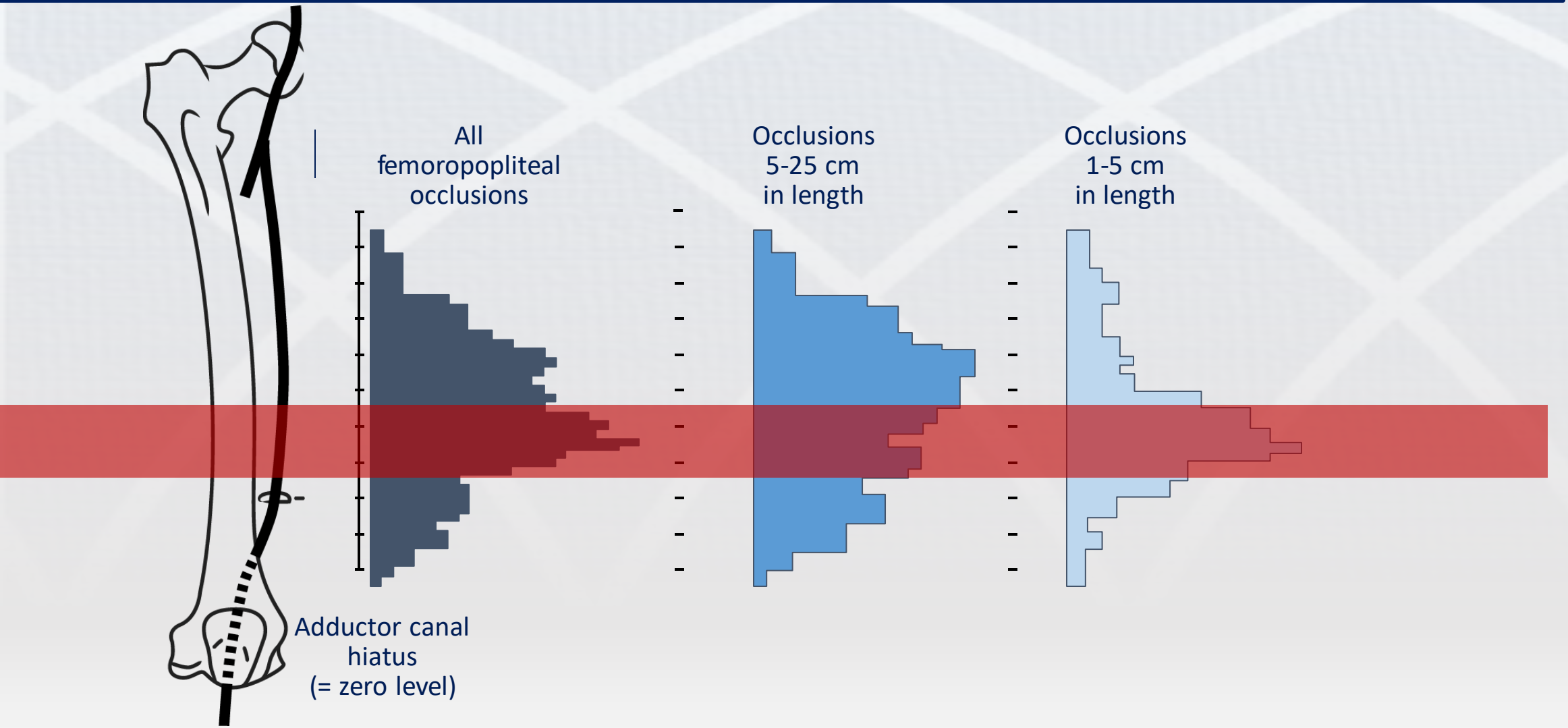
Cheng, C.P. et al.
In Vivo MRA Quantification of Axial/Twisting Deformations of the SFA
J Vasc Interv Radiol. 2006;17(6):979–987

Nikanorov A. et al.
Assessment of Self Expanding Nitinol Stent Deformation After Chronic Implantation in the SFA
J Vasc Surg. 2008;48(2):435–440.

Supinski, G.S. et al.
Effect of DiaphragmaticContraction on Intramuscular Pressure & Vascular Impedance
J Appl Physiol. 1990;68(4):1486–1493.

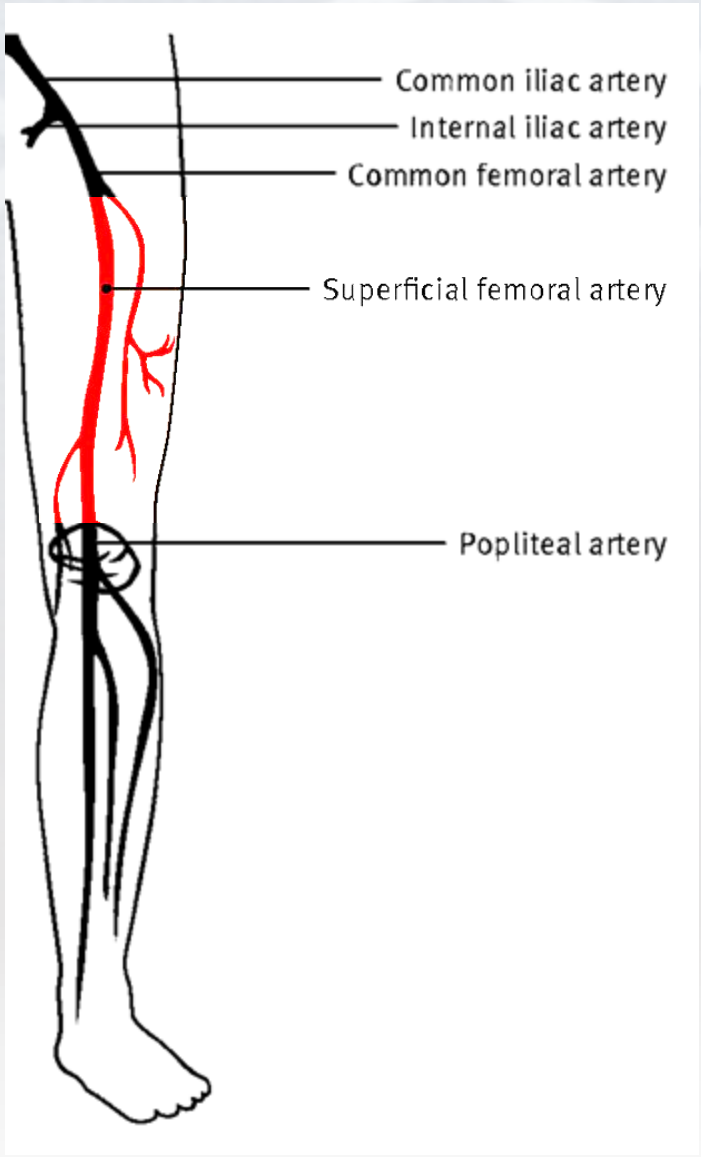


Plaque formation in the Femoral Artery Commonly Occurs in the Distal Portion of the Vessel



Scholten F et al. Eur J Vasc Surg. 1993 Nov;7(6):680-3.

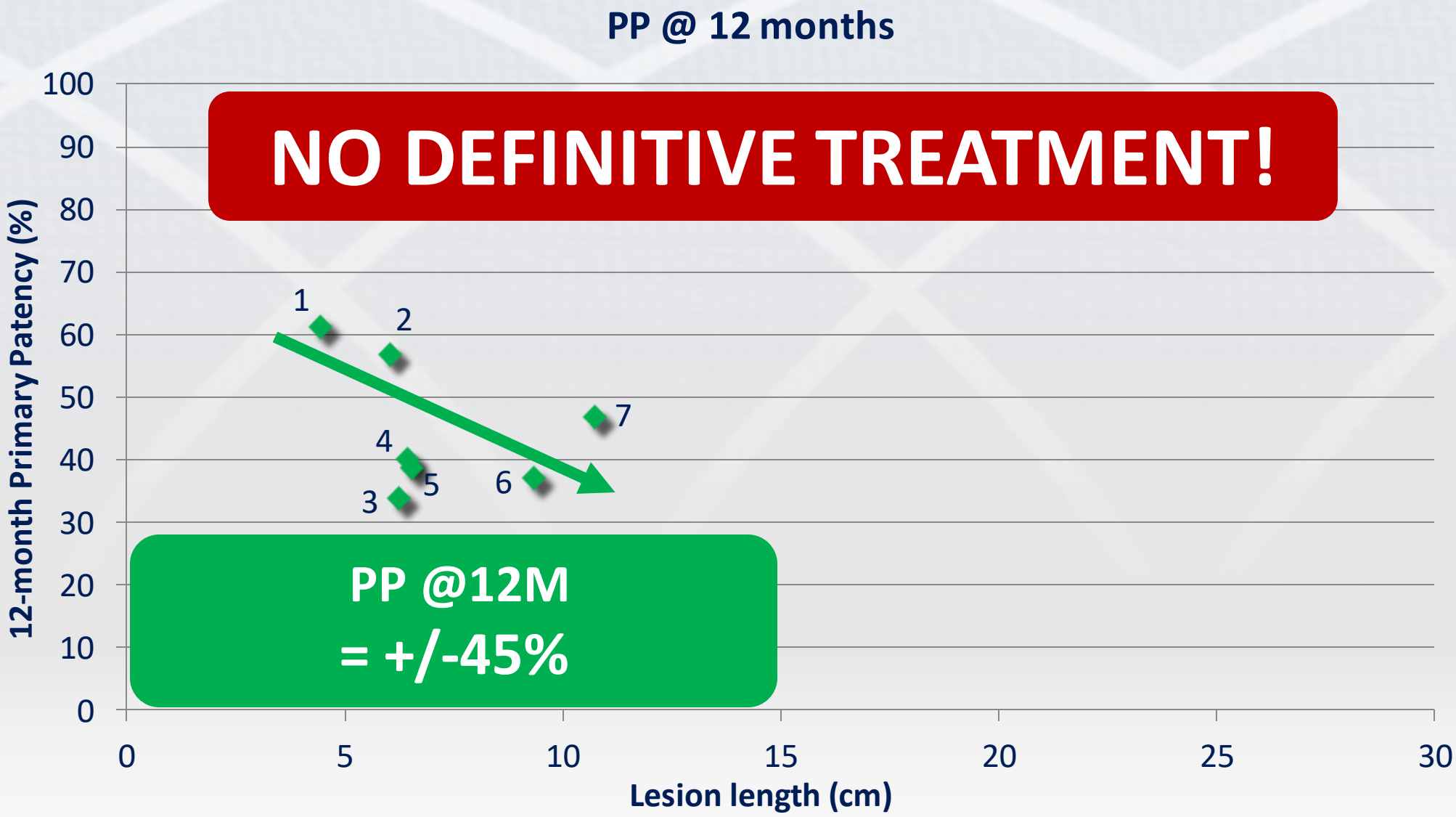
Superficial Femoral Artery



1. Femoropopliteal Artery

- Plain Old Balloon Angioplasty

In the beginning… there was only POBA



NO DEFINITIVE TREATMENT!

PP @12M
= +/-45%

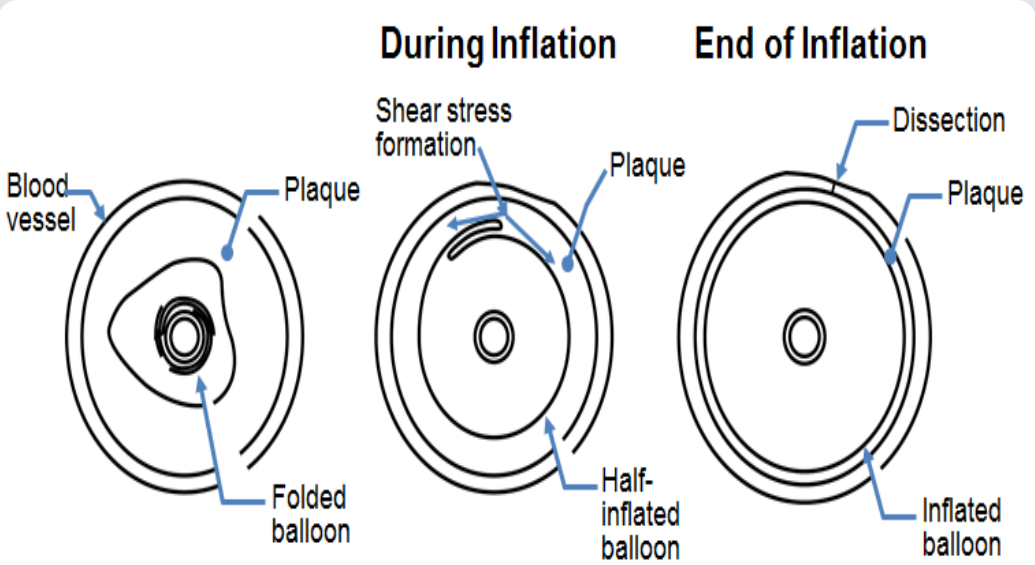
POBA

1. FAST
2. ZILVER PTX
3. RESILIENT
4. Saxon
5. ASTRON
6. VIENNA
7. VIENNA-3

Limitations of angioplasty in the SFA

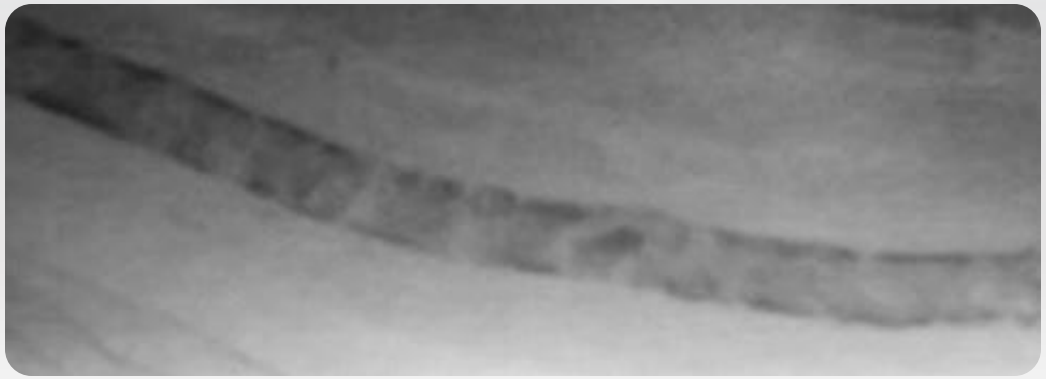
Addresses Dissection

-



Limitations of angioplasty in the SFA

Provides Scaffolding	-
Resists Acute Recoil	-

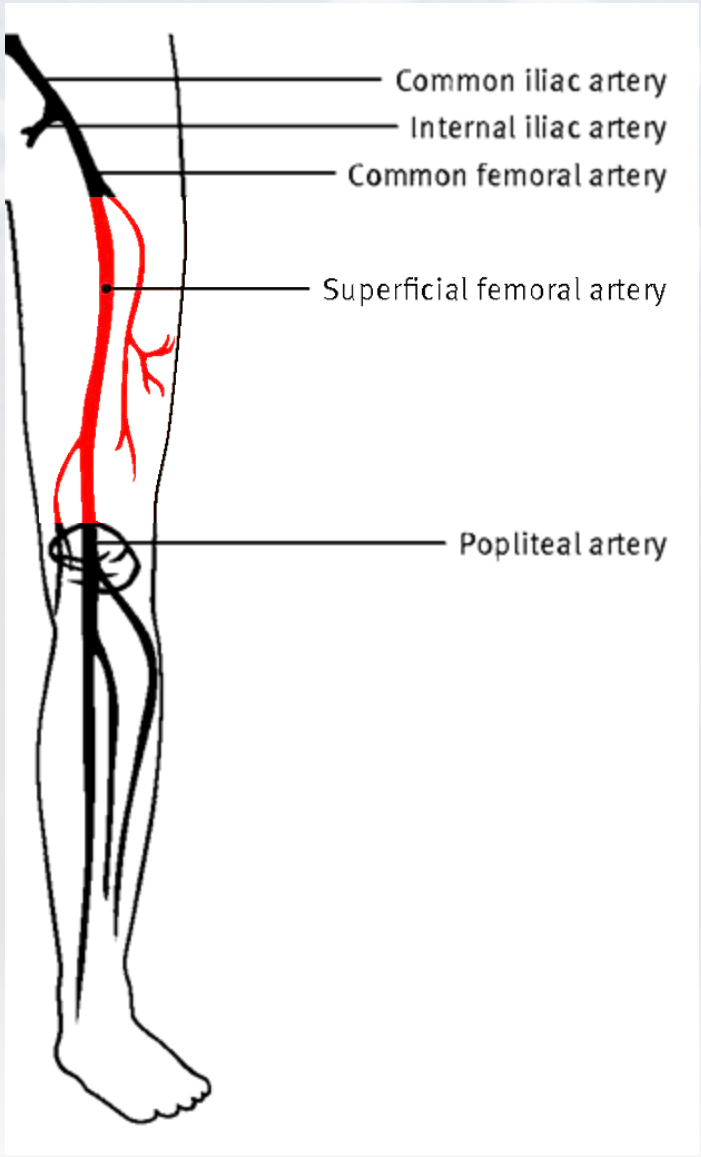


Limitations of angioplasty in the SFA

- **PTA study (2002)**
  - 74 patients
  - 43% major dissections
  - 32% residual stenosis >30%
- **ABSOLUTE: Stent vs. PTA (2006)**
  - 104 patients, 1:1 randomization
  - 32% insufficient PTA result led to cross over to stent
- **RESILIENT: Stent vs. PTA (2008)**
  - 206 patients 2:1 randomization 40% PTA cross over to stent due to flow limiting dissections and residual stenosis

High level of bail-out stenting!

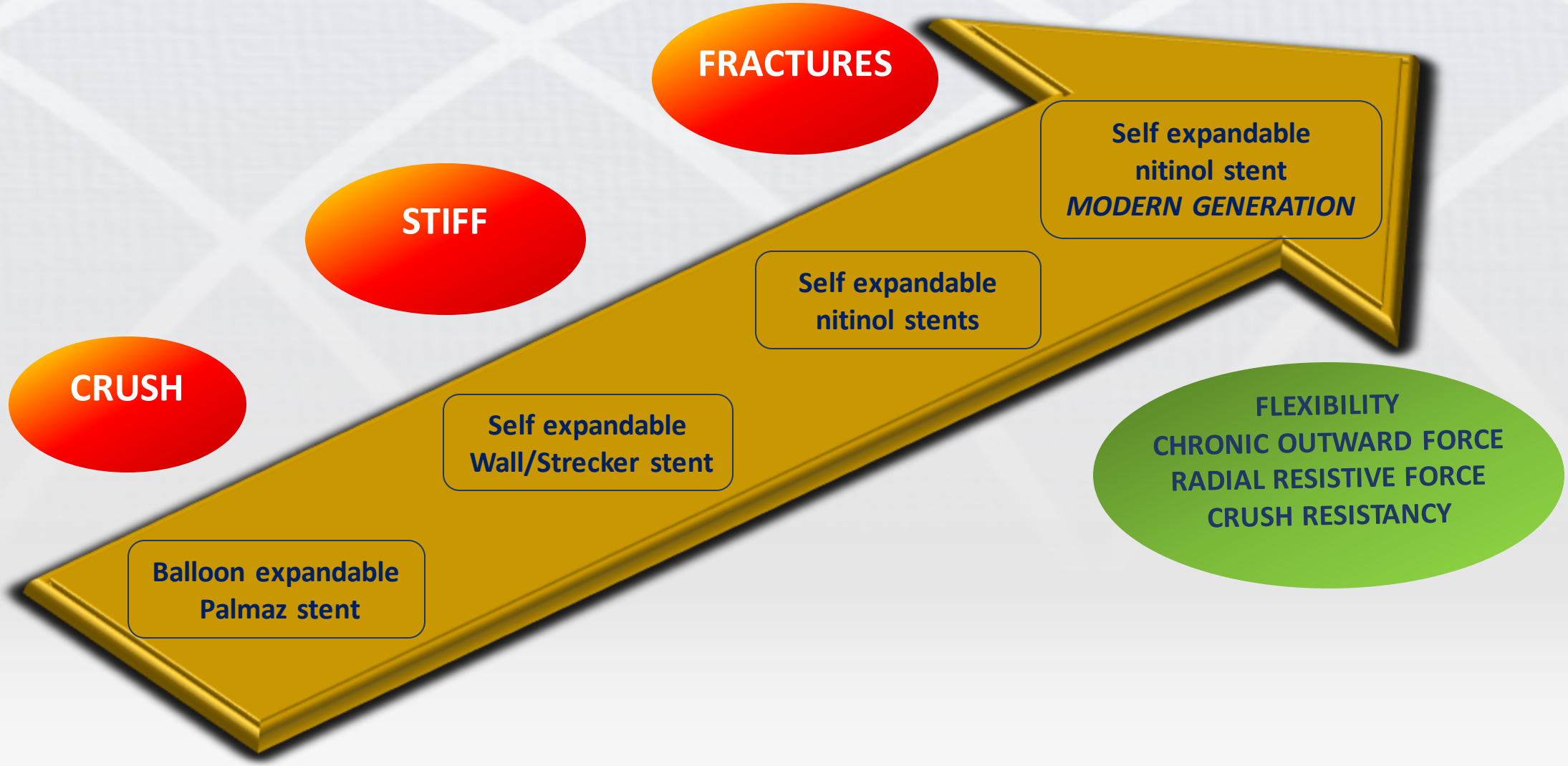
Superficial Femoral Artery



1. Femoropopliteal Artery

- Plain Old Balloon Angioplasty
- Bare Metal Stenting

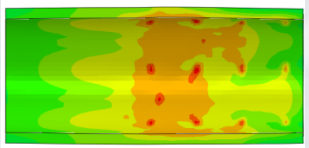
Introduction of scaffolding stents

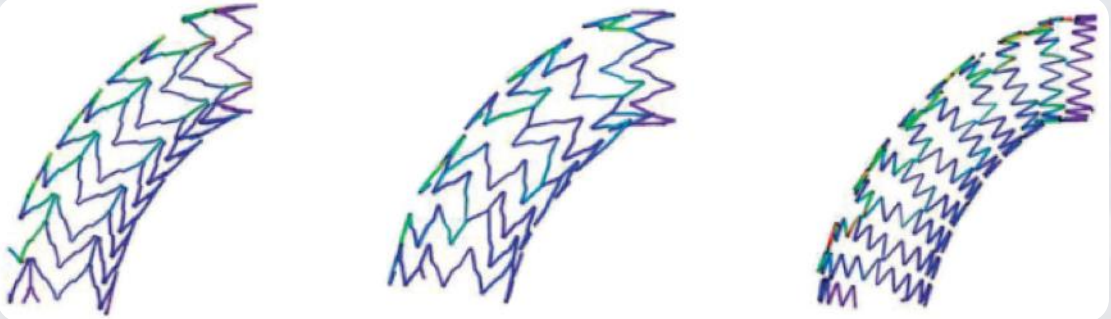


Stent design affects flexibility

Finite Element Analysis: Bending (red = high strain)

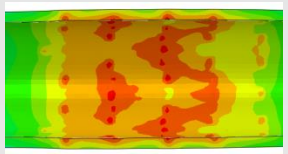
Low Stiffness

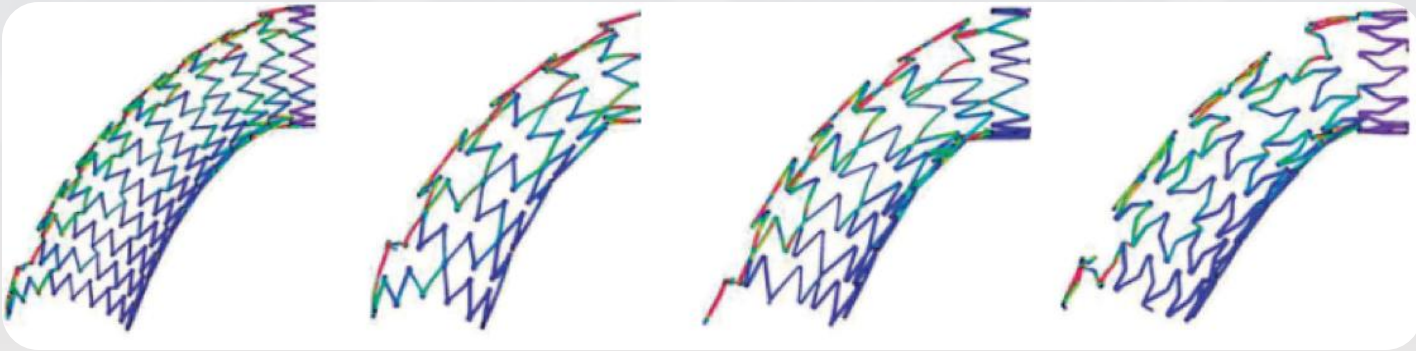




Absolute® Misago® Lifestent NT®

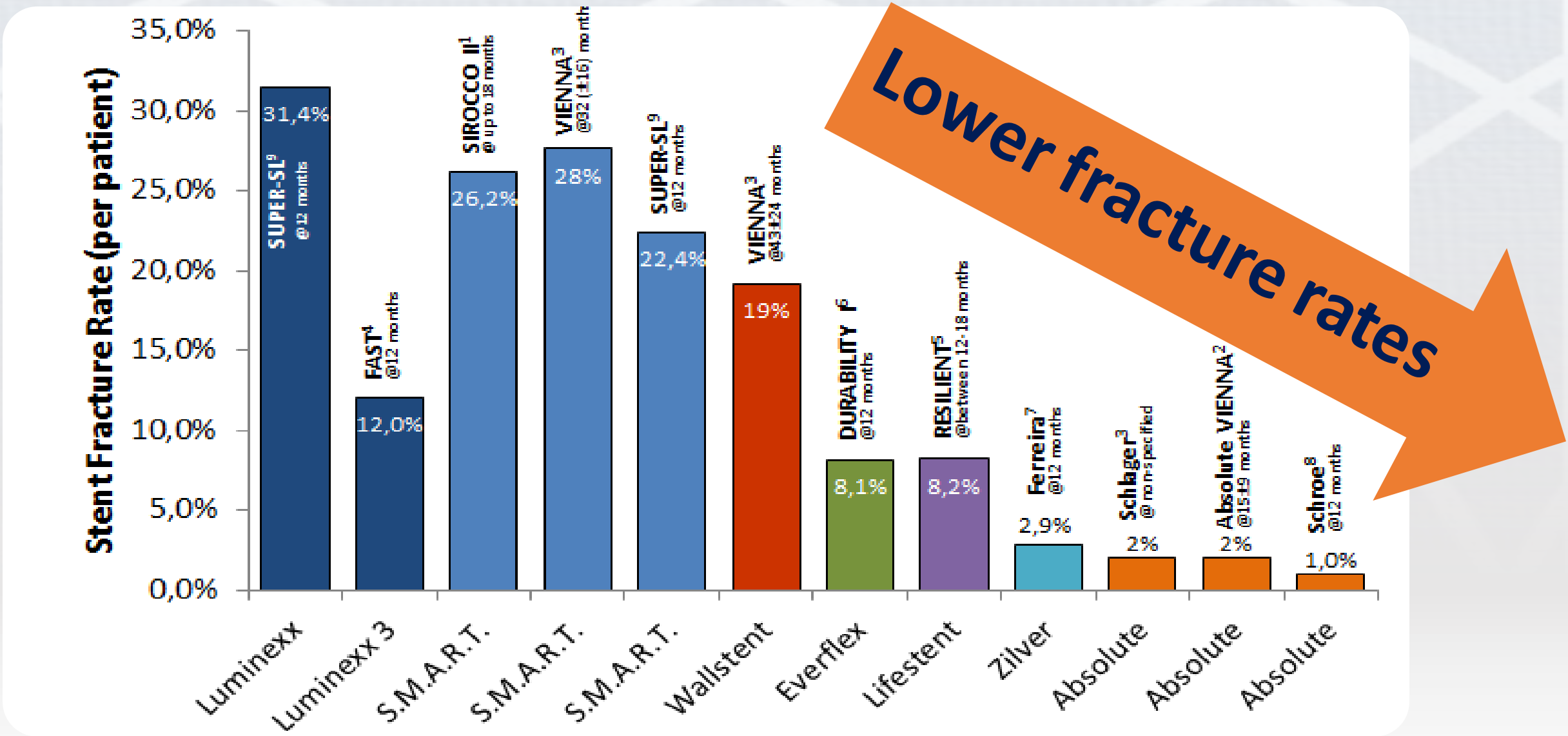
High Stiffness





S.M.A.R.T® Luminexx® Sentinol® Sinus-Superflex®

Modern generation of nitinol SES

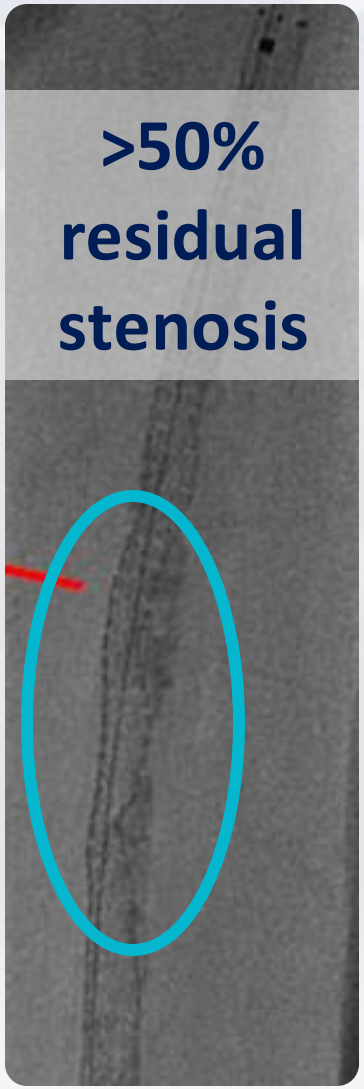


Stent design affects Chronic Outward Force

TOO LOW

Impossible to open the lesion

Residual stenosis

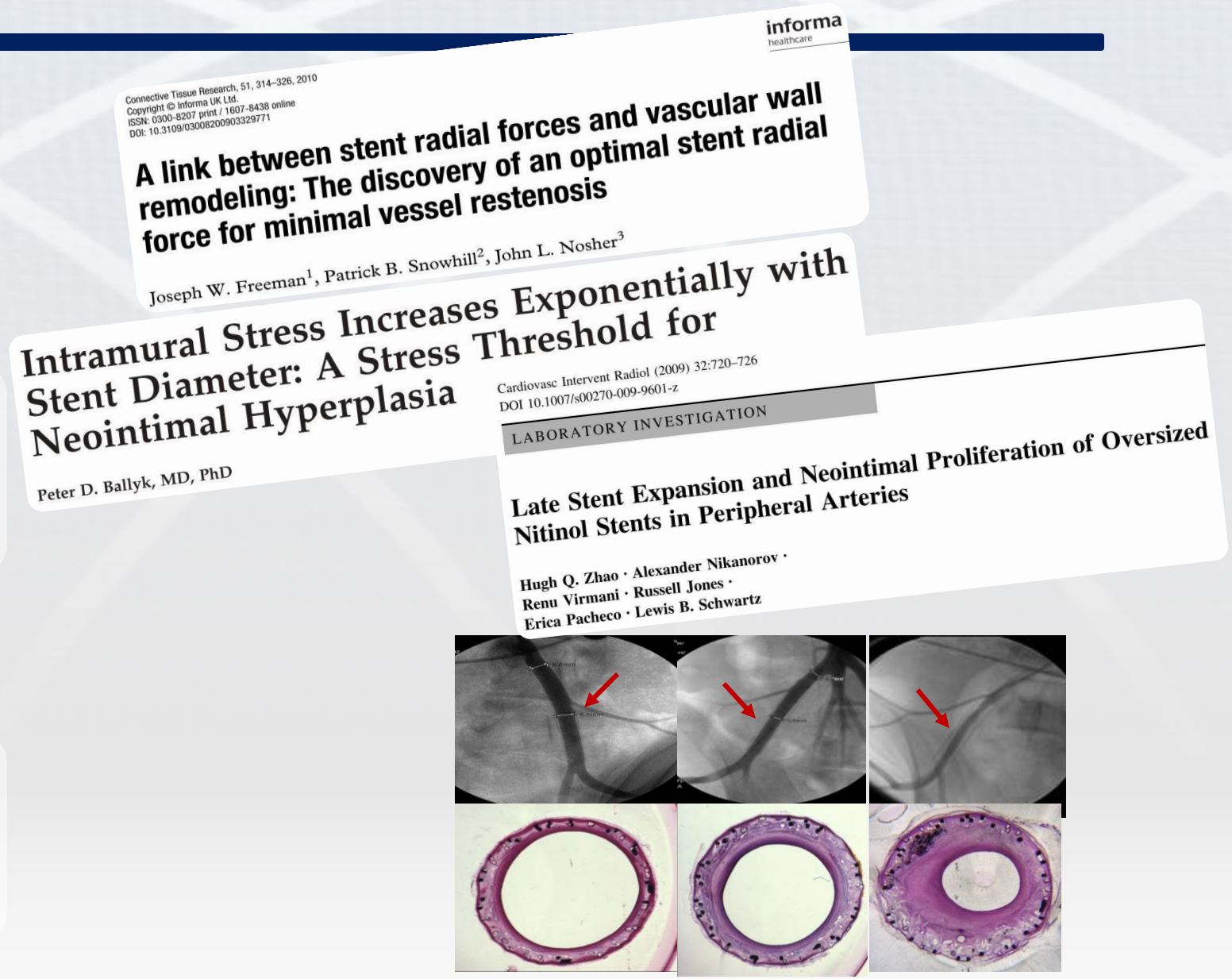


Stent design affects Chronic Outward Force

TOO HIGH

chronic stent-vessel irritation

intimal hyperplasia



Connective Tissue Research, 51, 314–326, 2010
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DOI: 10.3109/03008200903329771

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healthcare

A link between stent radial forces and vascular wall remodeling: The discovery of an optimal stent radial force for minimal vessel restenosis

Joseph W. Freeman[1], Patrick B. Snowhill[2], John L. Nosher[3]

Intramural Stress Increases Exponentially with Stent Diameter: A Stress Threshold for Neointimal Hyperplasia

Peter D. Ballyk, MD, PhD

Cardiovasc Intervent Radiol (2009) 32:720–726
DOI 10.1007/s00270-009-9601-z

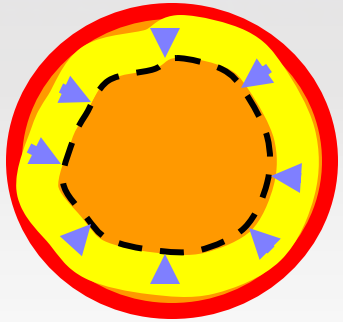
LABORATORY INVESTIGATION

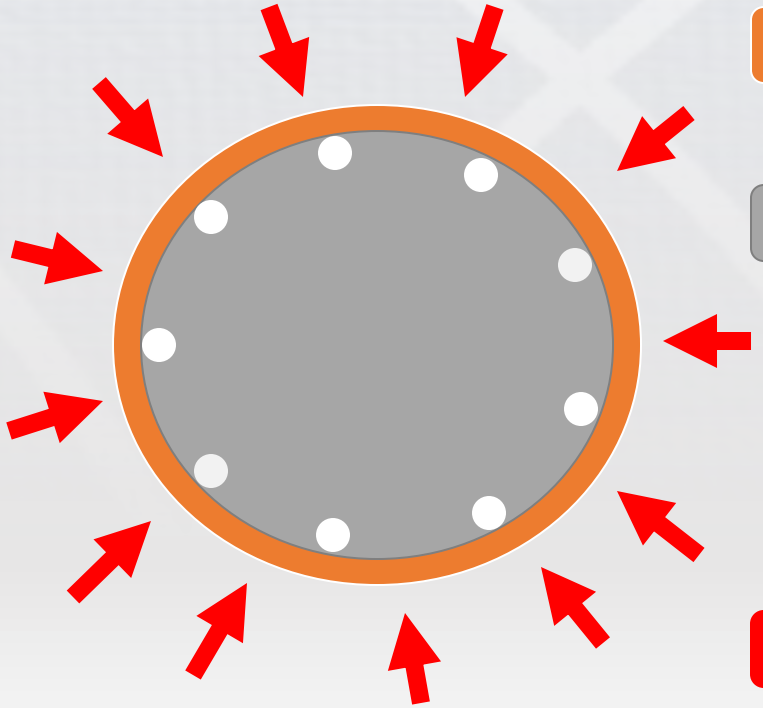
Late Stent Expansion and Neointimal Proliferation of Oversized Nitinol Stents in Peripheral Arteries

Hugh Q. Zhao · Alexander Nikanorov · Renu Virmani · Russell Jones · Erica Pacheco · Lewis B. Schwartz

Stent design affects Radial Resistive Force

Resistive force exerted by self expanding stents to resist ***CONCENTRIC*** squeezing by the artery (concentric restenosis) or other external factors

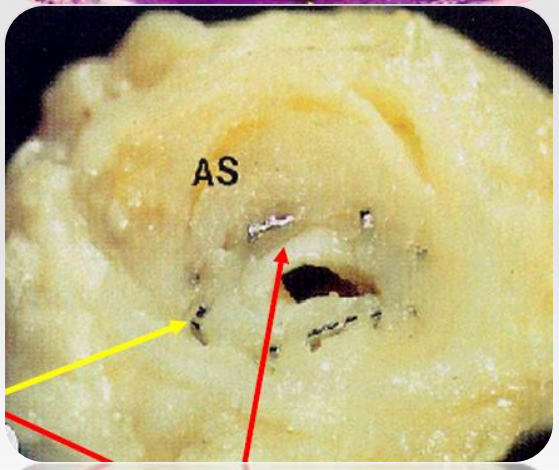




Vessel Wall

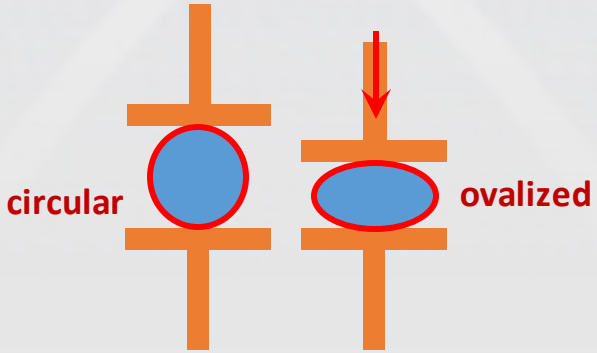
Stent Placement

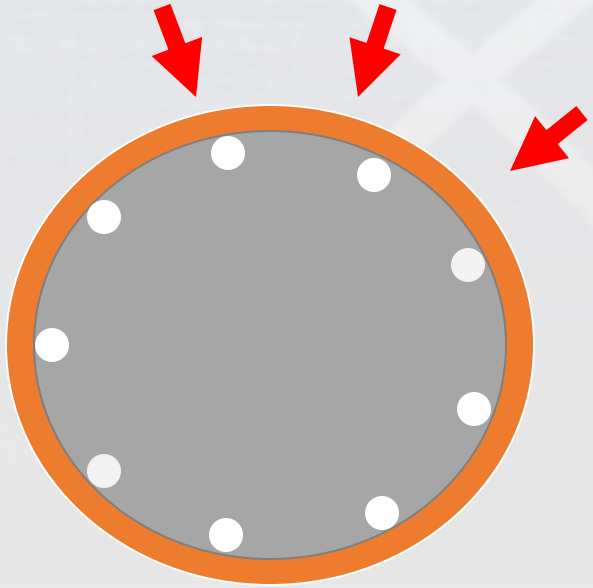
Stent RRF



Stent design affects Crush Resistance

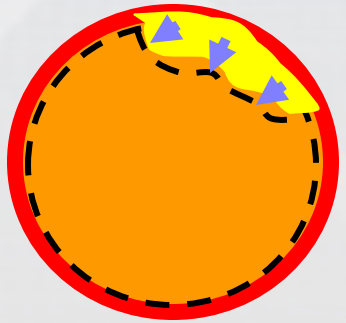
Crush resistance exerted by self expanding stents to resist ***ECCENTRIC***, focal compression of the artery (external finger pinching or eccentric restenosis)





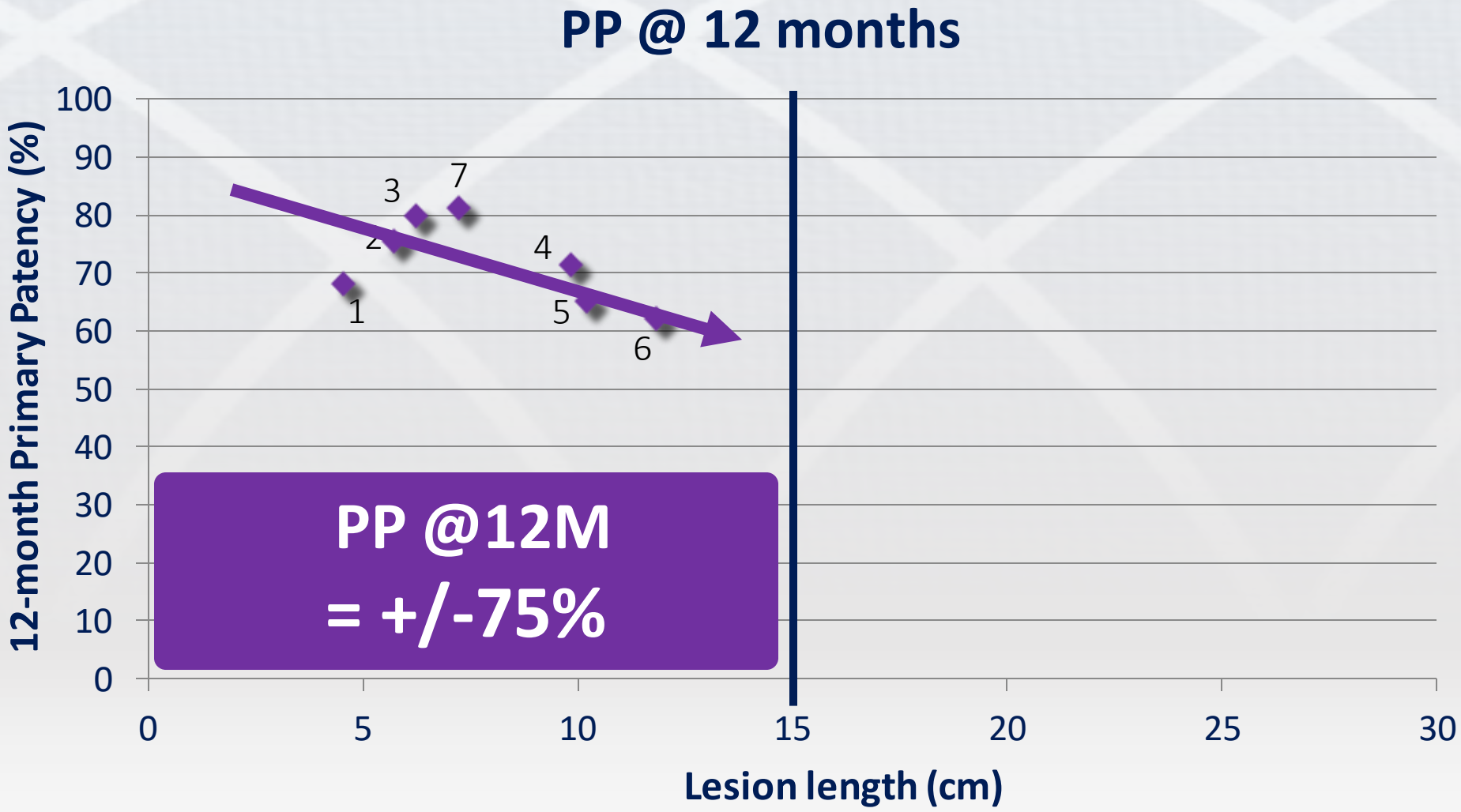
Vessel Wall

Stent Placement



Stent RRF

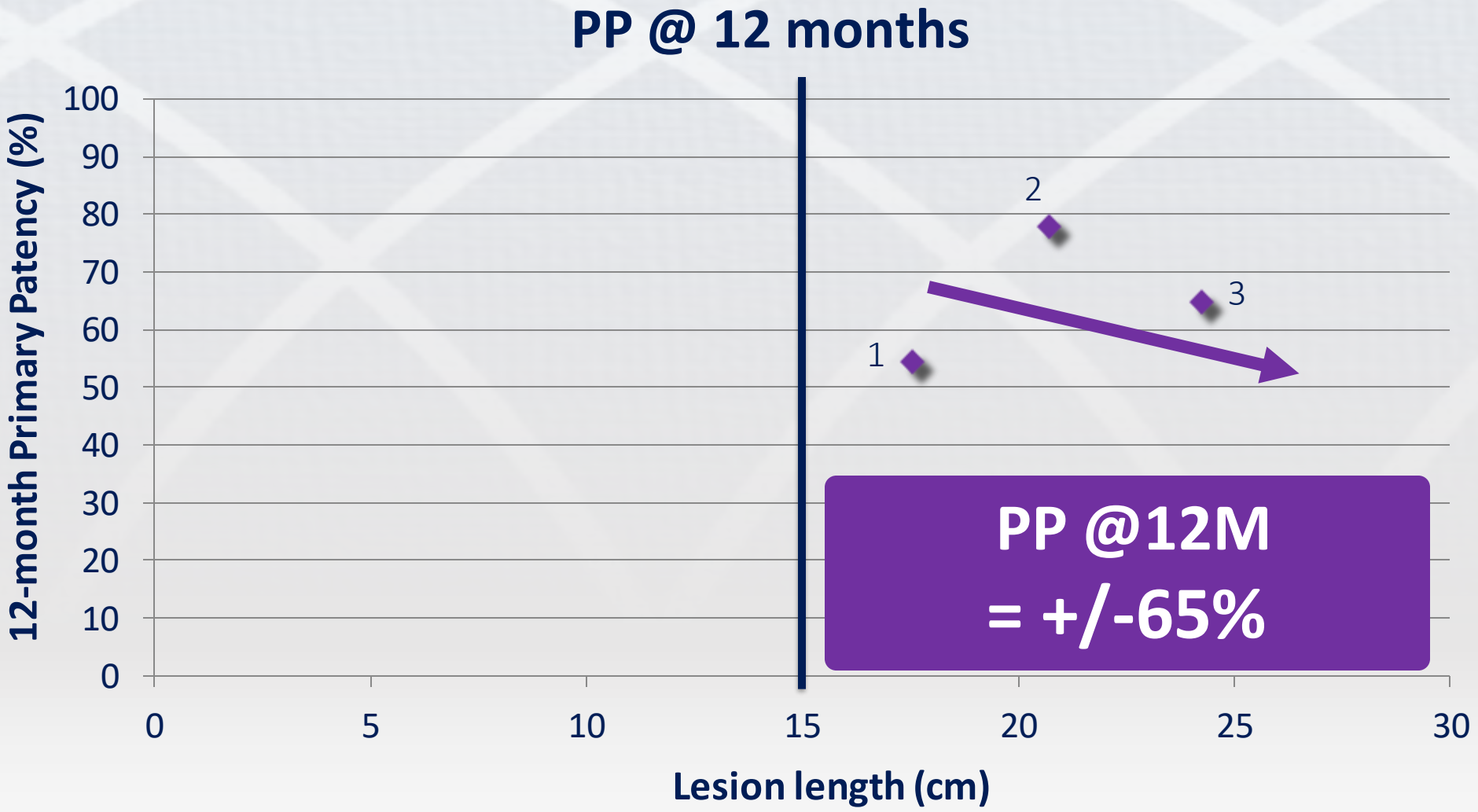
Results with BMS in the SFA



Stent

1. FAST
2. FACT
3. RESILIENT
4. DURABILITY
5. ASTRON
6. VIENNA
7. 4EVER

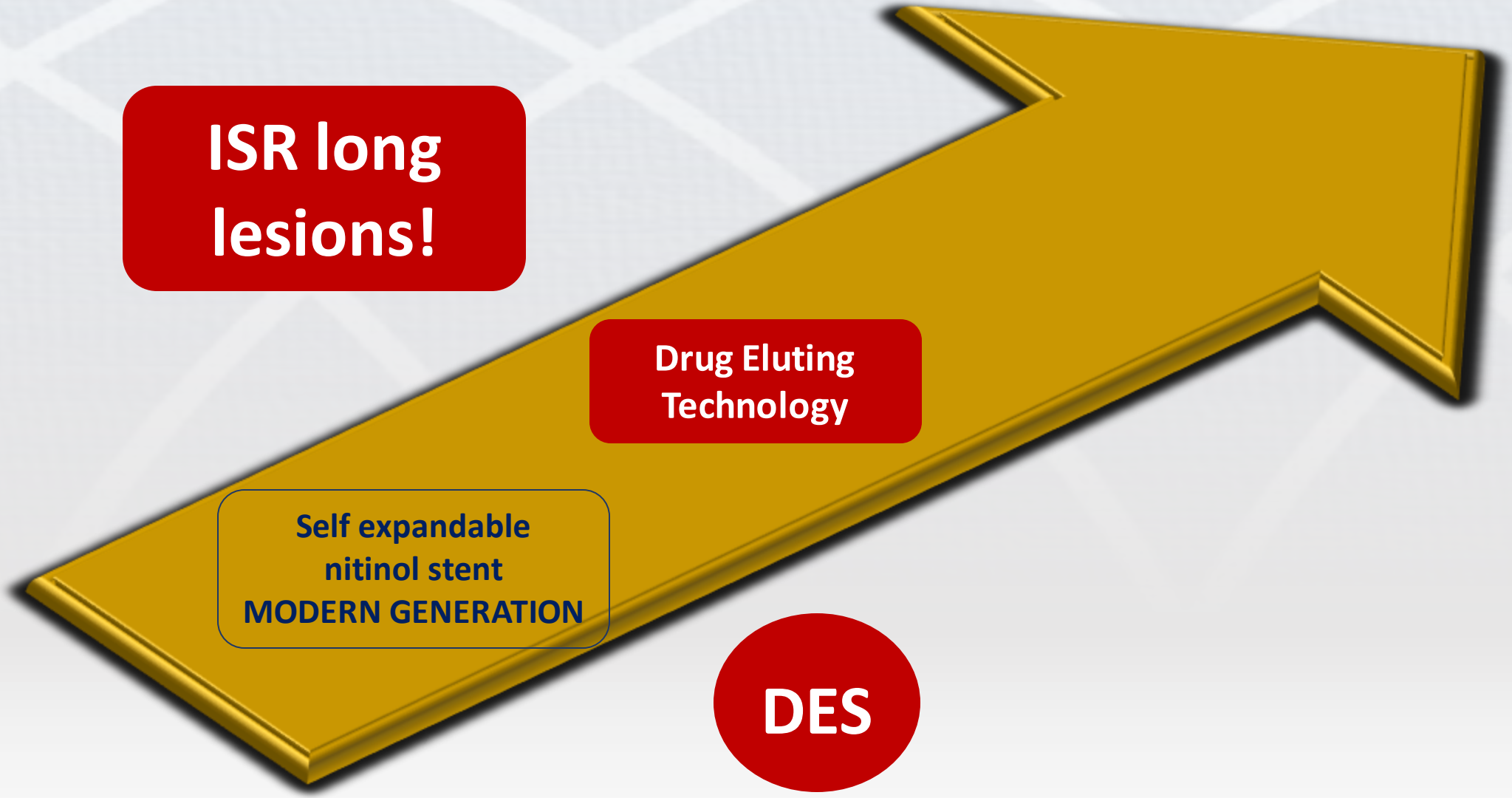
Results with BMS in the SFA



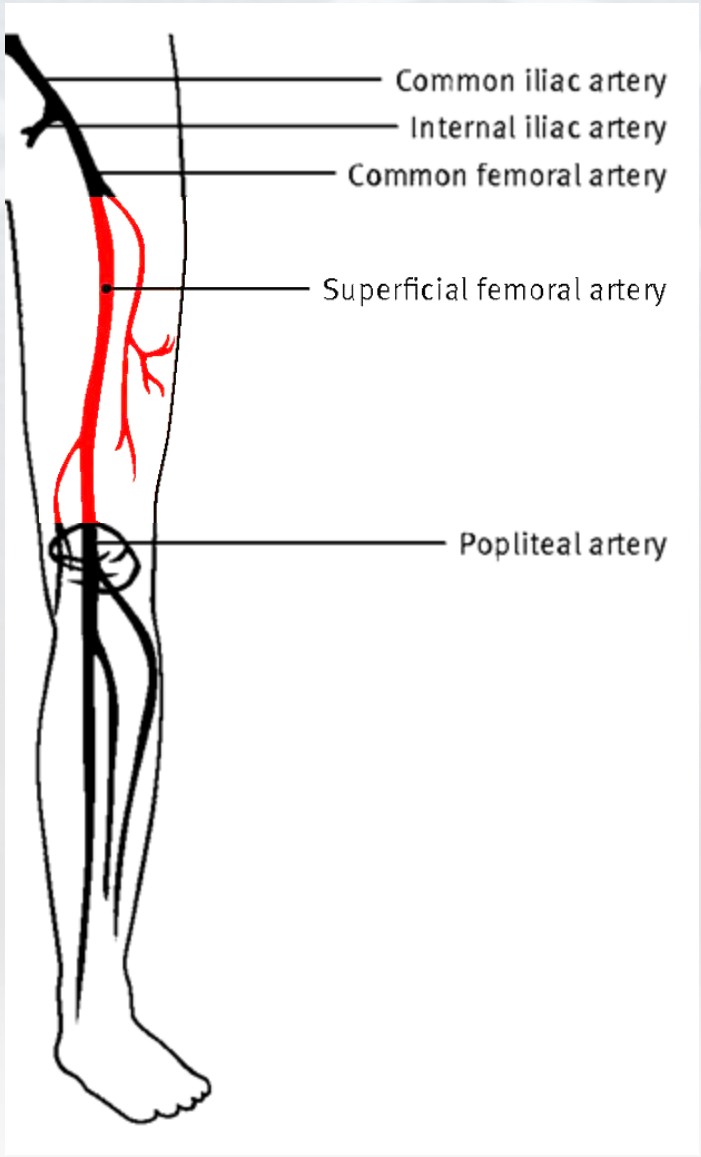
Stent

1. VIASTAR: BMS
2. VIASTAR: Viabahn
3. DURABILITY-200

There is still room for improvement…



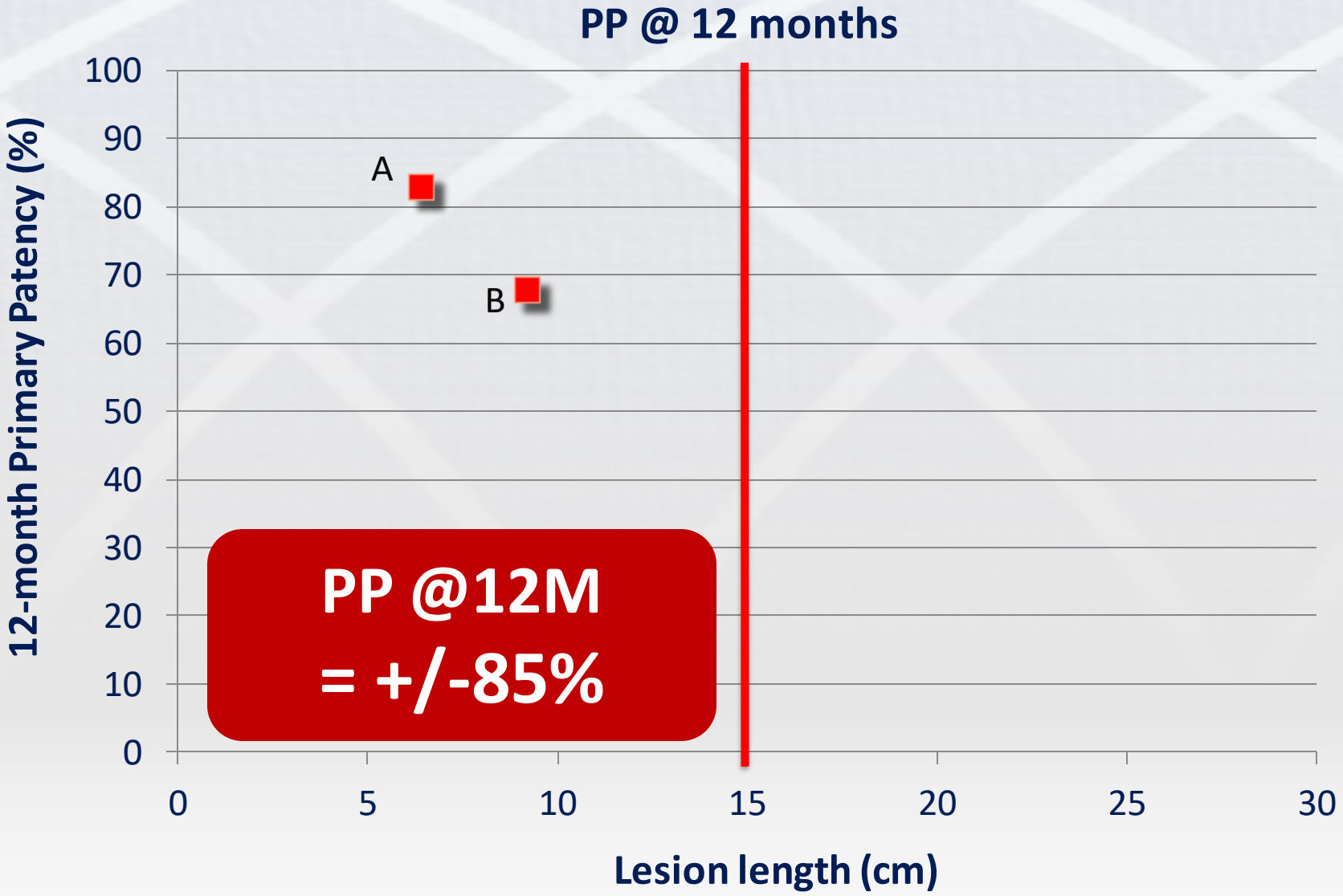
Superficial Femoral Artery



1. Femoropopliteal Artery

- Plain Old Balloon Angioplasty
- Bare Metal Stenting
- Drug Eluting Stenting

Results with DES in the SFA

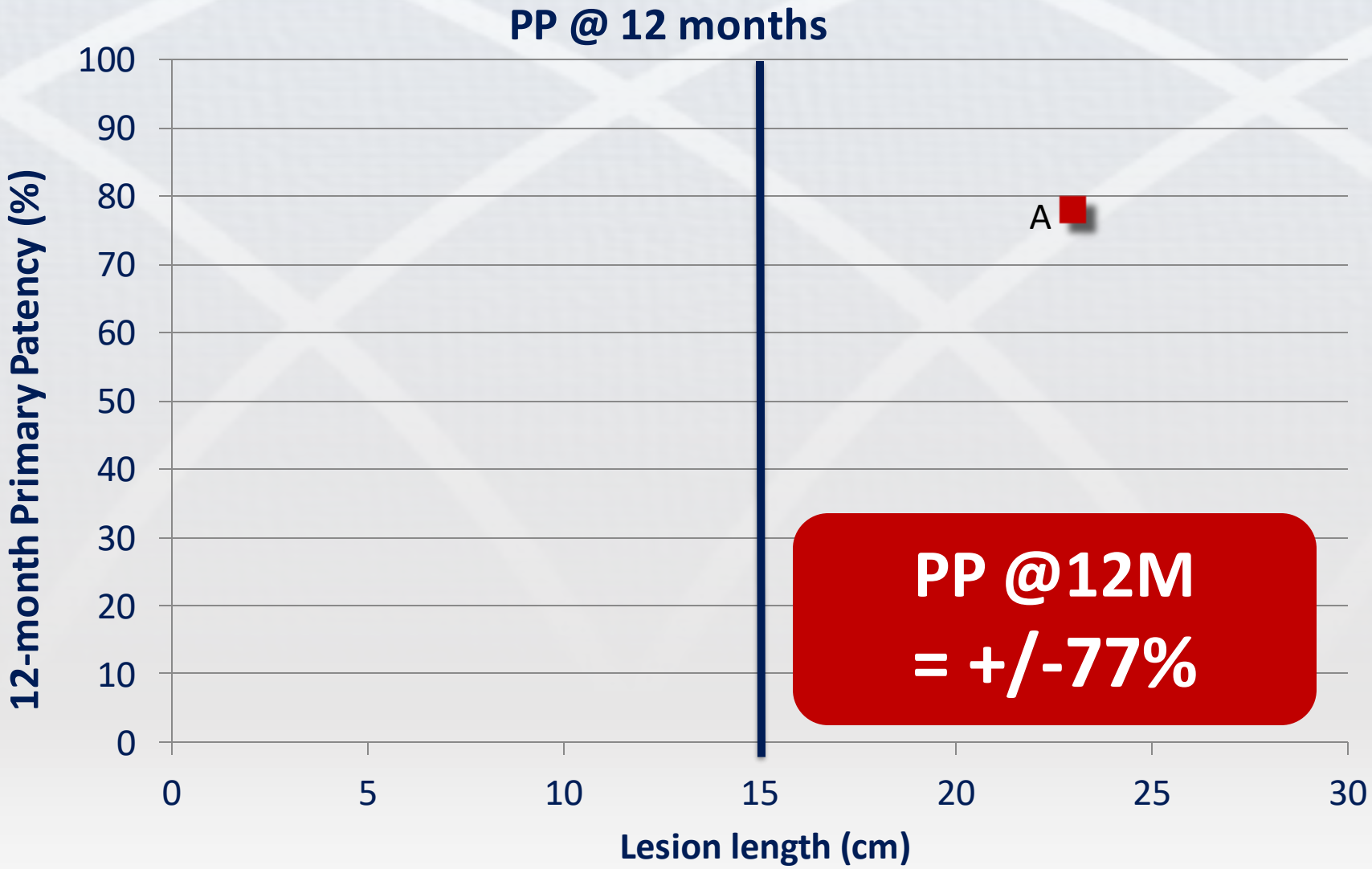


DES

A. ZILVER PTX

B. STRIDES

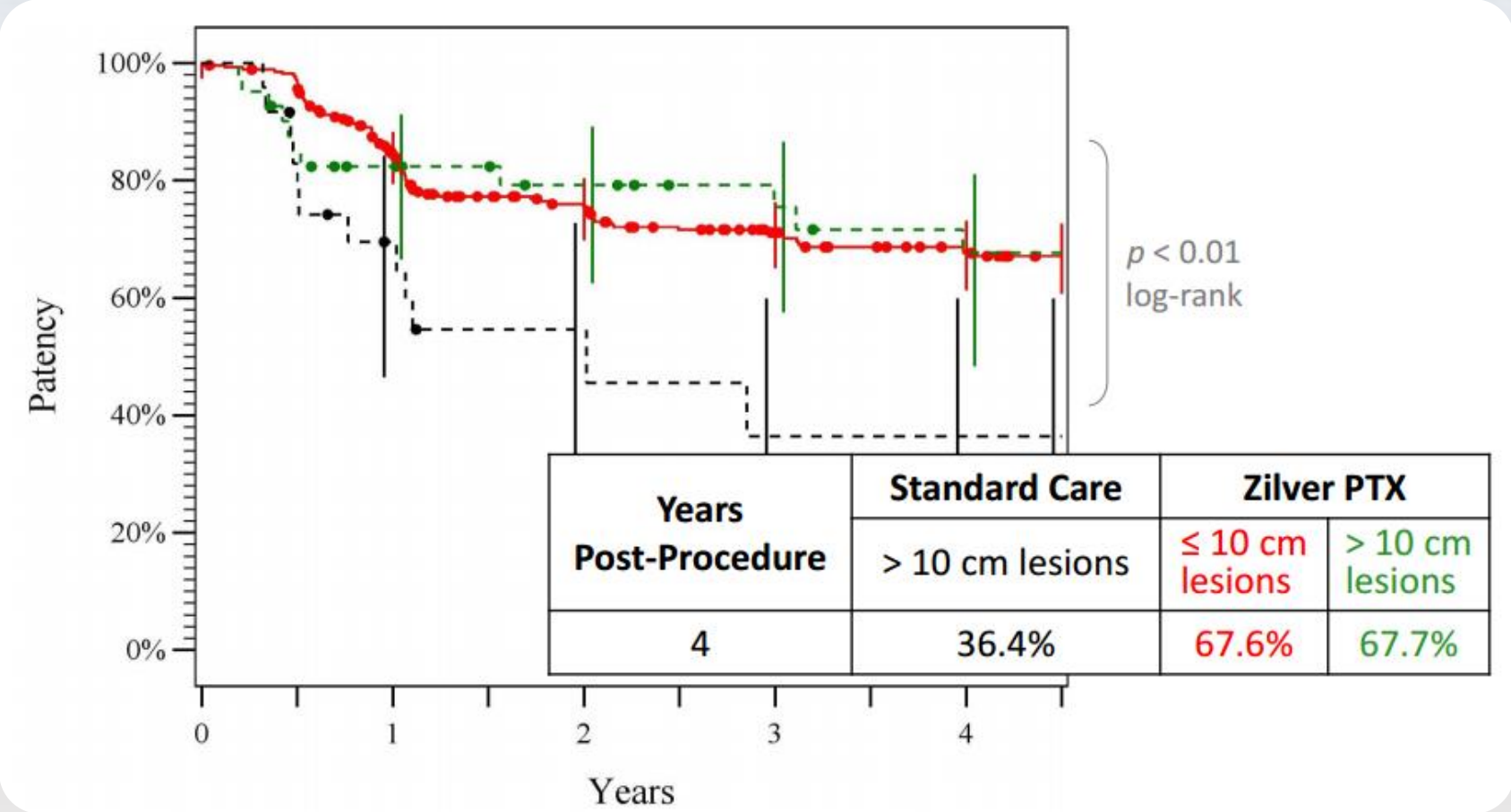
Results with DES in the SFA



DES

A. ZILVER PTX

Results with DES in the SFA



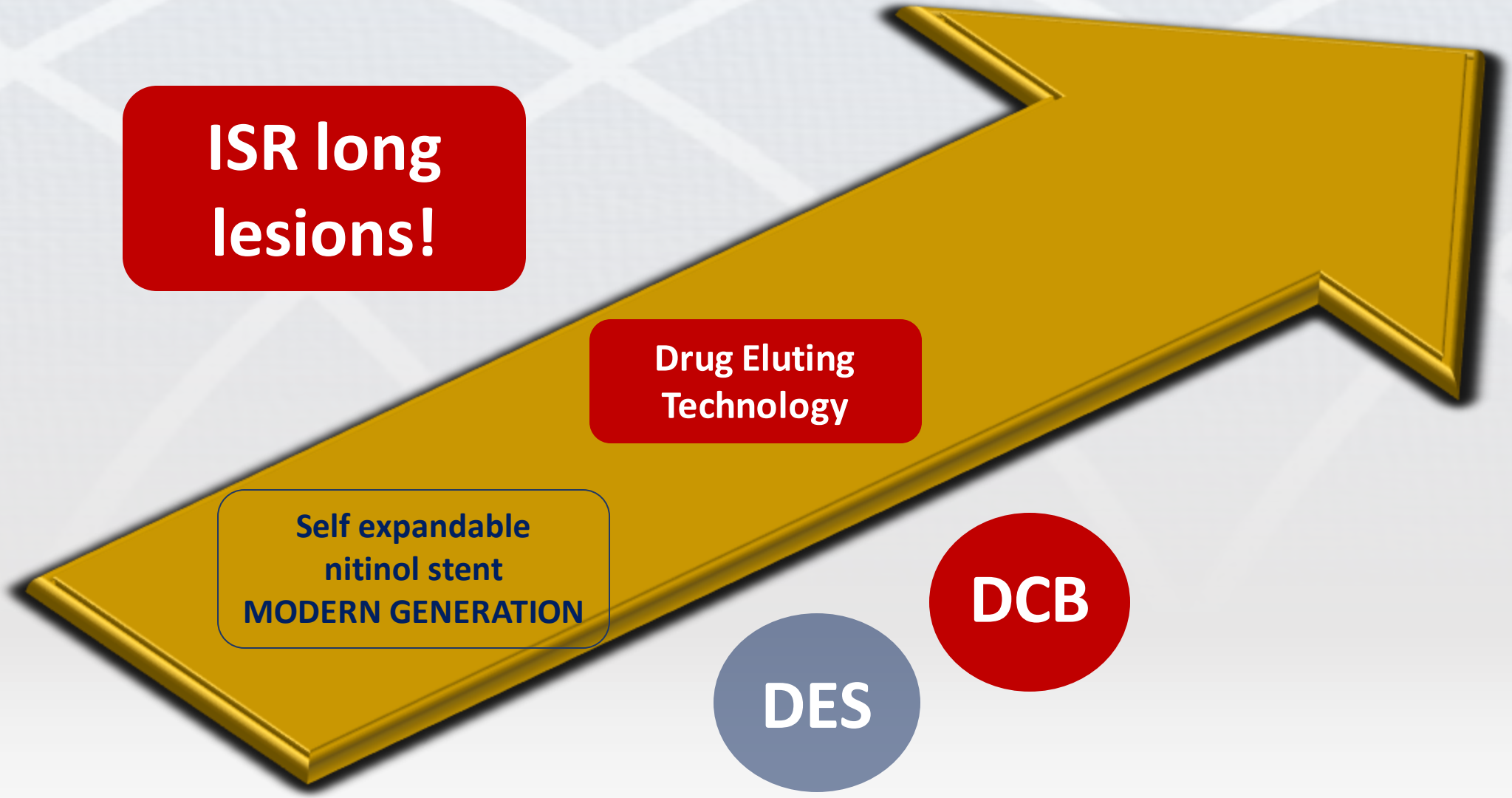
Years Post-Procedure	Standard Care	Zilver PTX	
	> 10 cm lesions	≤ 10 cm lesions	> 10 cm lesions
4	36.4%	67.6%	67.7%

Good results, even on the long turn & in longer lesions!

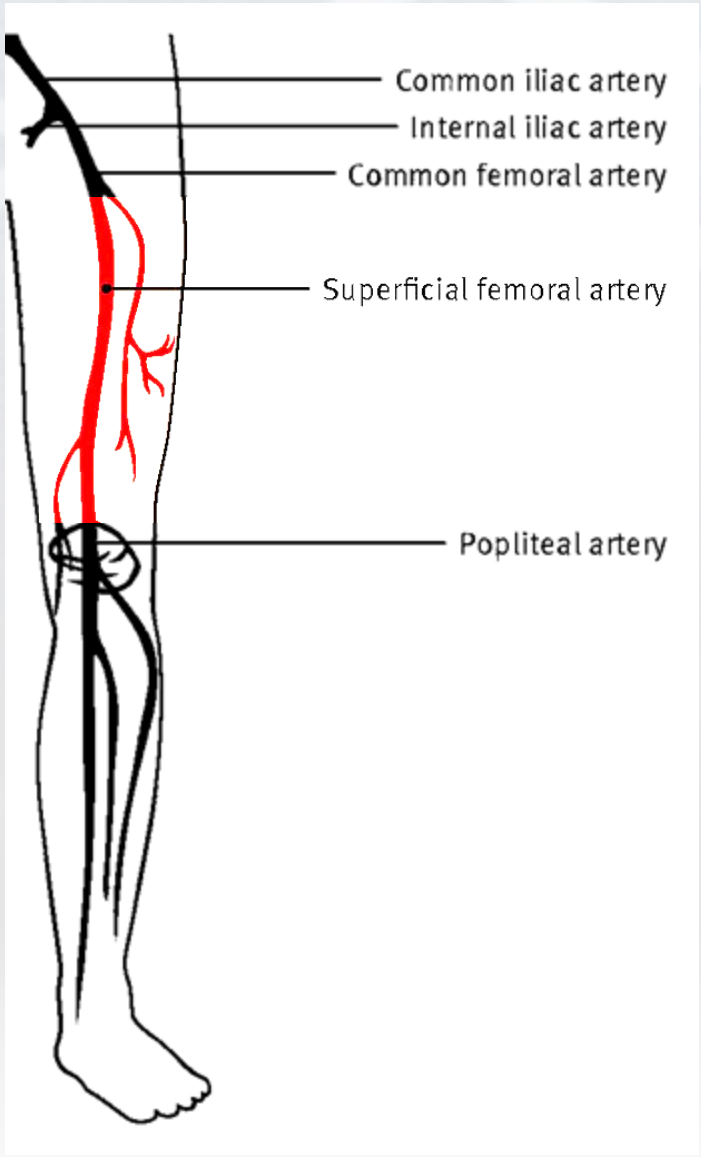
Limitations of DES in the SFA

- Cost-Effectiveness of treatment
- Short length of available devices
- Only 1 platform – study (Zilver PTX)
- Coral reef calcifications?
- Permanent implant!

There is still room for improvement…



Superficial Femoral Artery

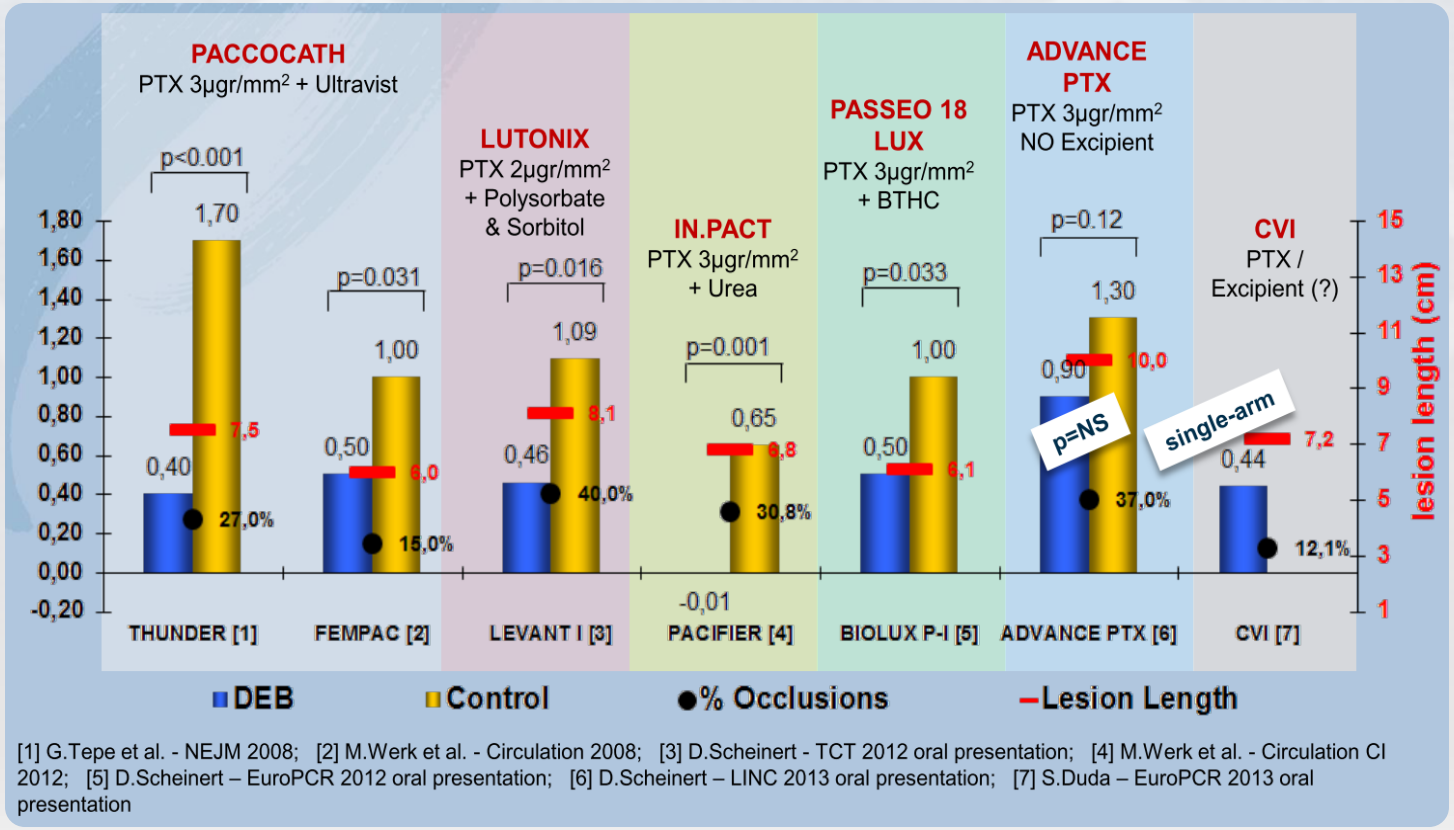


1. Femoropopliteal Artery

- Plain Old Balloon Angioplasty
- Bare Metal Stenting
- Drug Eluting Stenting
- Drug Coated Balloon

Drug Coated Balloons…

PROOF OF CONCEPTS



[1] G.Tepe et al. - NEJM 2008; [2] M.Werk et al. - Circulation 2008; [3] D.Scheinert - TCT 2012 oral presentation; [4] M.Werk et al. - Circulation CI 2012; [5] D.Scheinert – EuroPCR 2012 oral presentation; [6] D.Scheinert – LINC 2013 oral presentation; [7] S.Duda – EuroPCR 2013 oral presentation

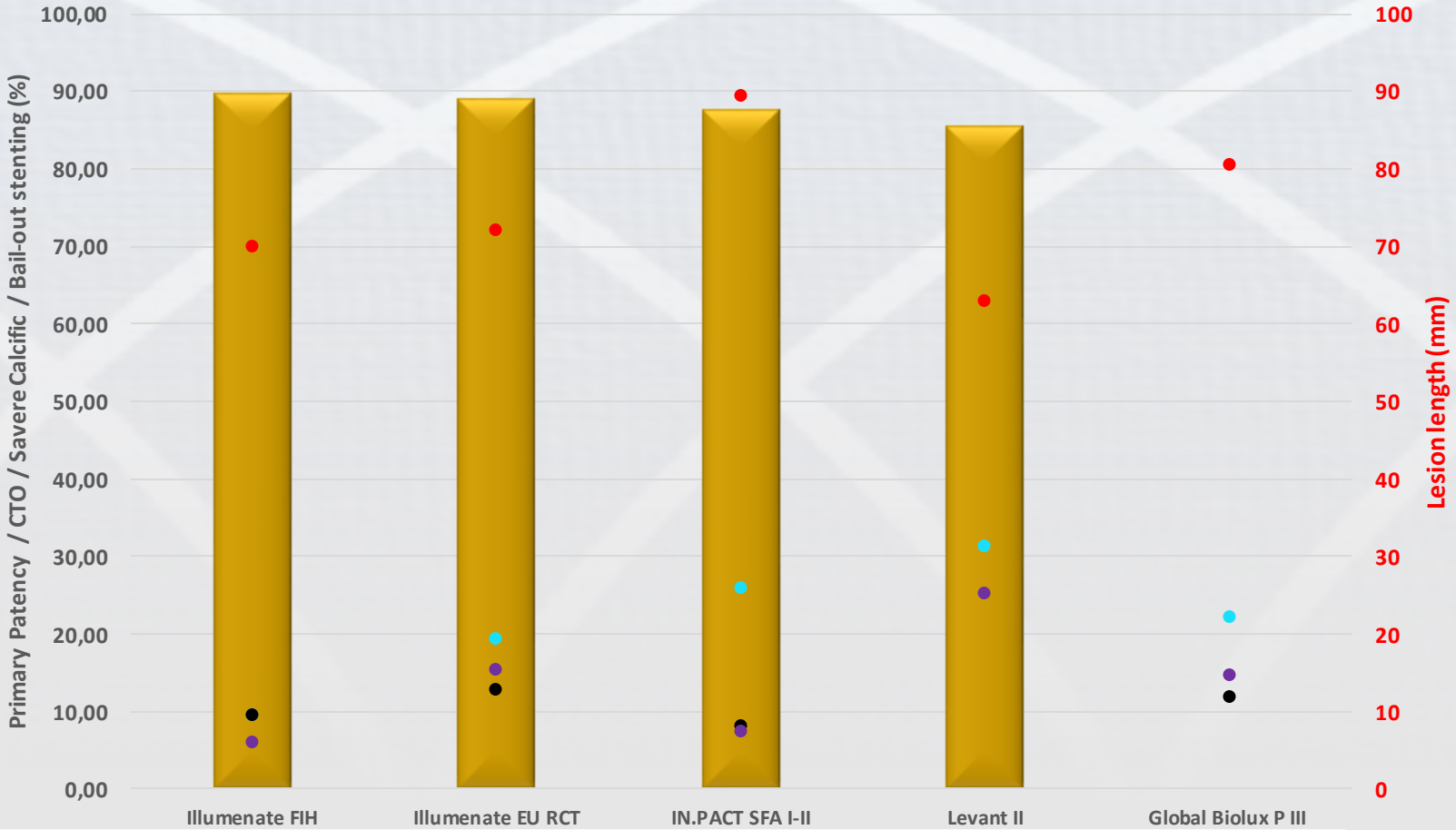
DCB is an added value compared to POBA alone

If you respect the correct inflation time

	Inflation Time (sec)		
	30 ⟷	180	*P* Value
Major dissection (grades 3 and 4)	16	5	.010
Minor or no dissection (grades 1 and 2)	21	32	.010
Further interventions	20	9	.017
Stent	4	1	
Further dilation (prolonged dilation, dilation with larger diameter)	16	8	
Residual stenosis (>30%)	12	5	.097

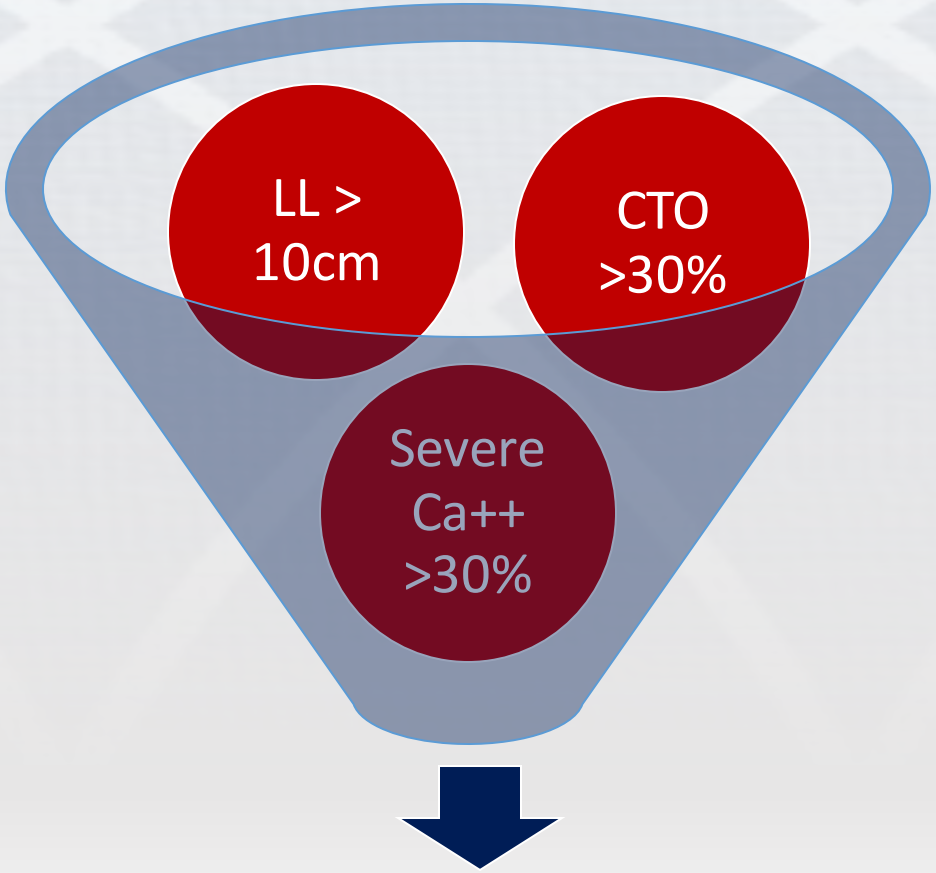
Zorget N et al. Peripheral arterial balloon angioplasty: effect of short vs long balloon inflation times on the morphologic results. J Vasc Interv Radiol. 2002 Apr;13(4):355-9

DCB treatment in “ideal circumstances”



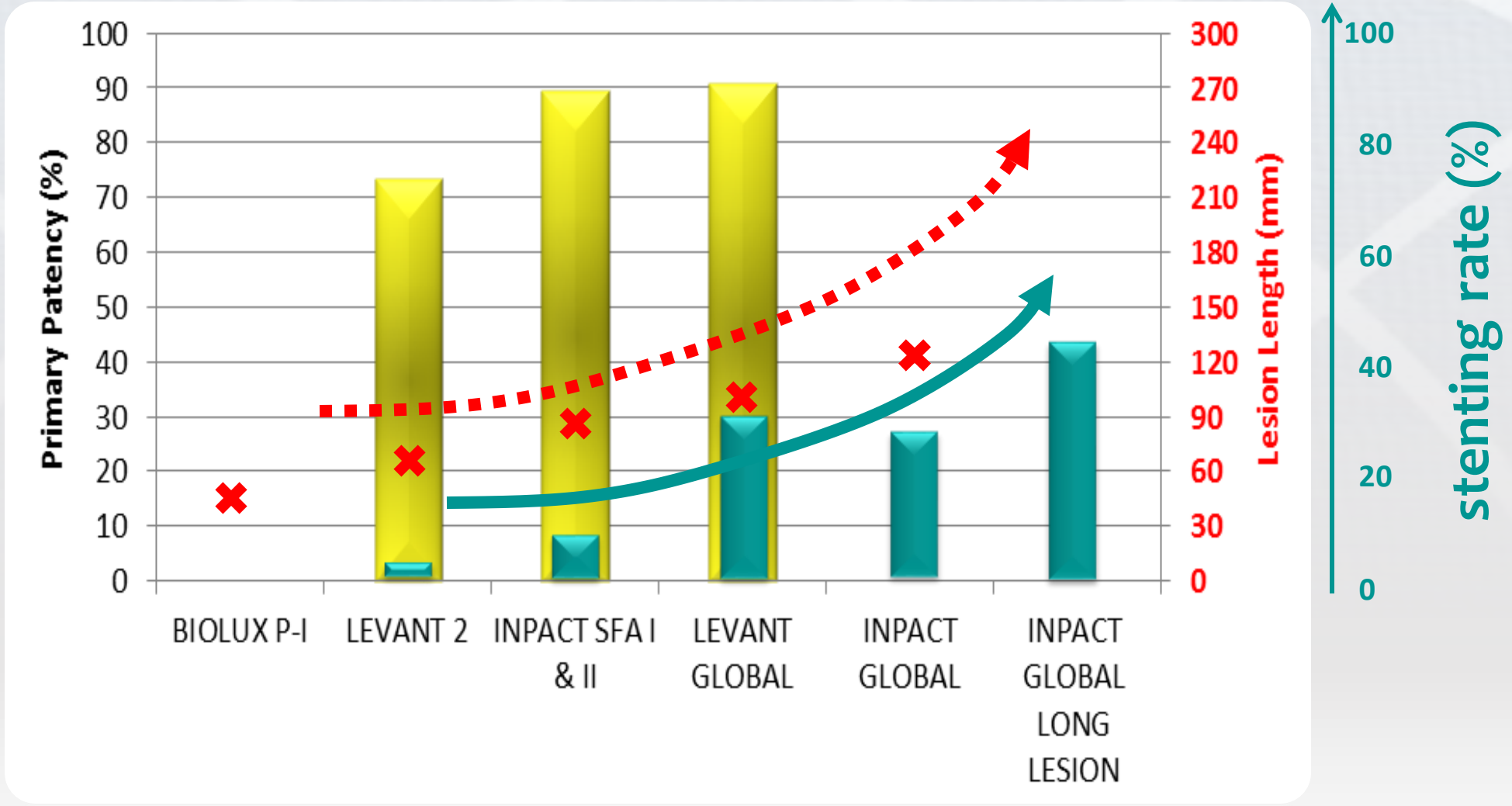
Primary Patency (%)	**89.50**	**89.00**	**87.50**	**85.40**	**N.A.**
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	25.2	14.5
% CTO	9.4	19.2	25.8	31.2	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7

However, real-world lesions…



"REAL LIFE" difficult outcomes

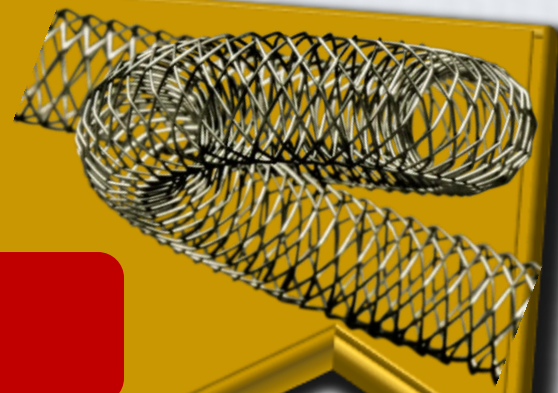
12-month Primary Patency stenting rate



There is still room for improvement…

Scaffolding?
Severe calcium
Longer lengths

Cost-Effectiveness
Short Length devices
Coral reef calcium
Permanent implant



VMI

Drug Eluting Technology

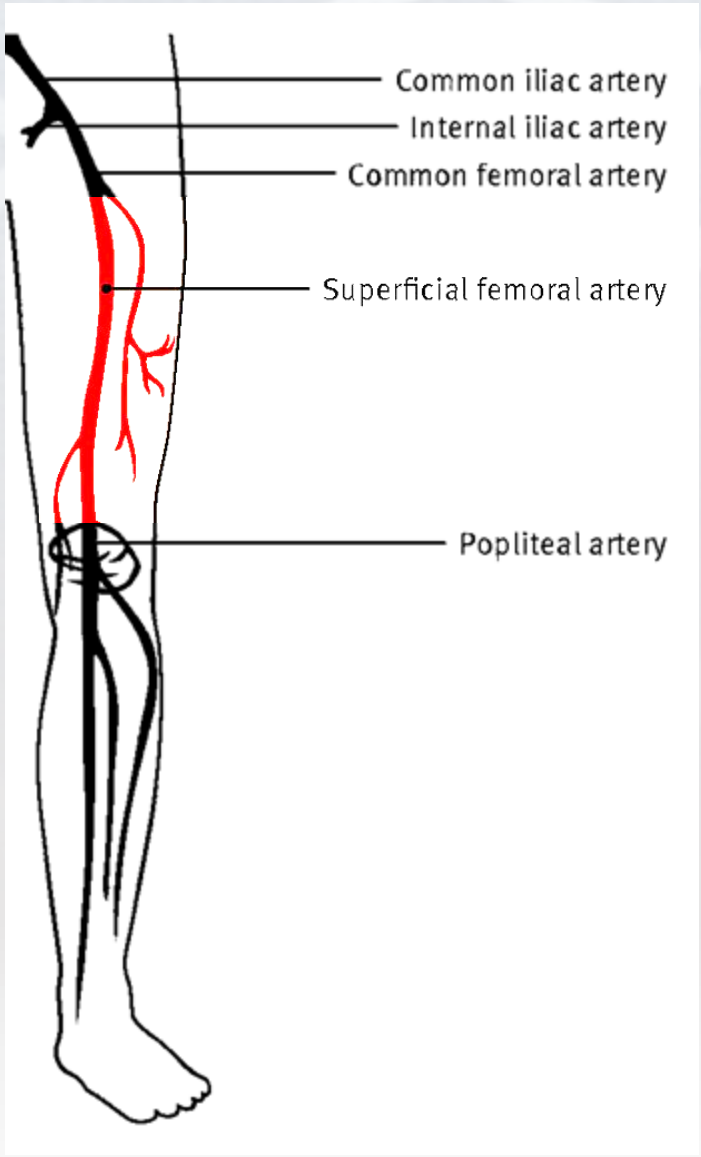
Self expandable nitinol stent MODERN GENERATION

DCB

DES

Ideal mechanical implant should *mimic* rather than *resist* the vessel

Superficial Femoral Artery



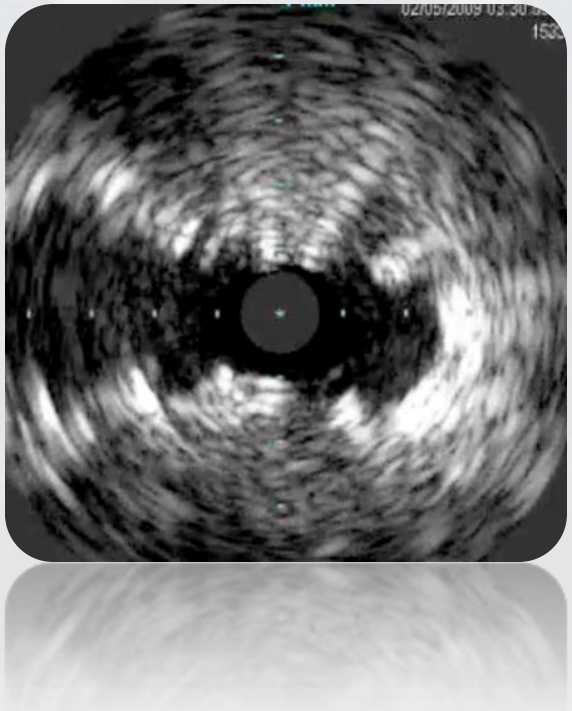
1. Femoropopliteal Artery

- Plain Old Balloon Angioplasty
- Bare Metal Stenting
- Drug Eluting Stenting
- Drug Coated Balloon Angioplasty
- Vascular Mimetic Implant

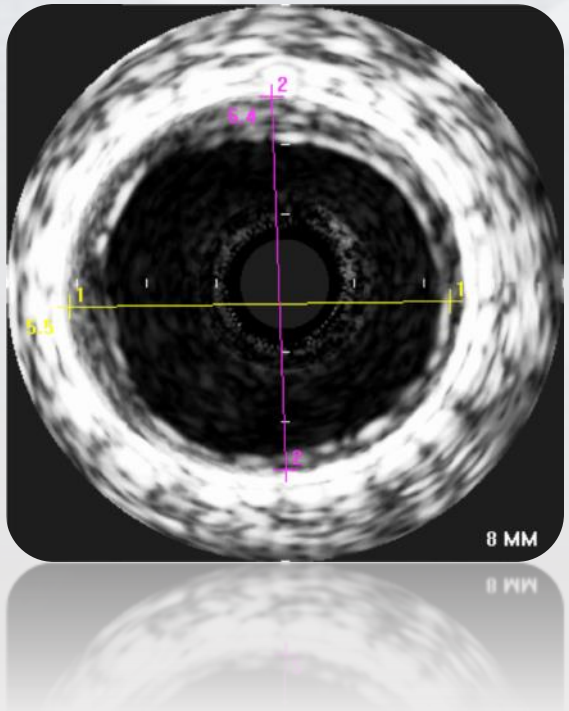
VMI Supera (Abbott Vascular)

Extremely High Crush Resistancy

Standard SE Nitinol stent



Supera



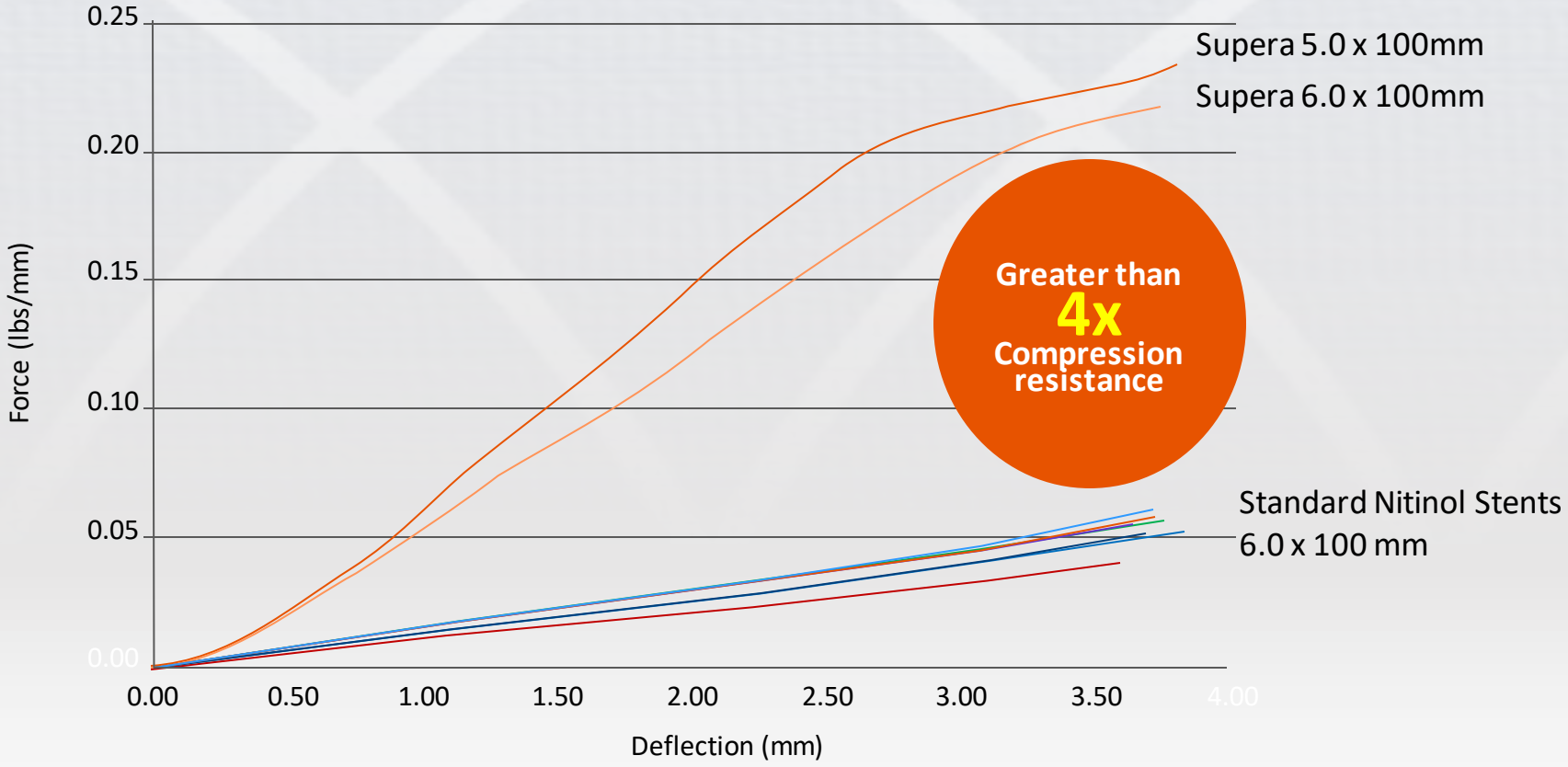
Maintains a visibly round, open lumen for normal flow in challenging anatomy

Standard nitinol stent IVUS image and characteristically round lumens supported by Arena, F.J., Arena, F.A. Intravascular Ultrasound Evaluation of Interwoven Nitinol Stents at Implant. J Vasc Med Surg. 2013:1;116.
Supera IVUS image courtesy of Dr. David Cohen, Valley Hospital, New Jersey, USA. X-ray image from SUPERB trial.

VMI Supera (Abbott Vascular)

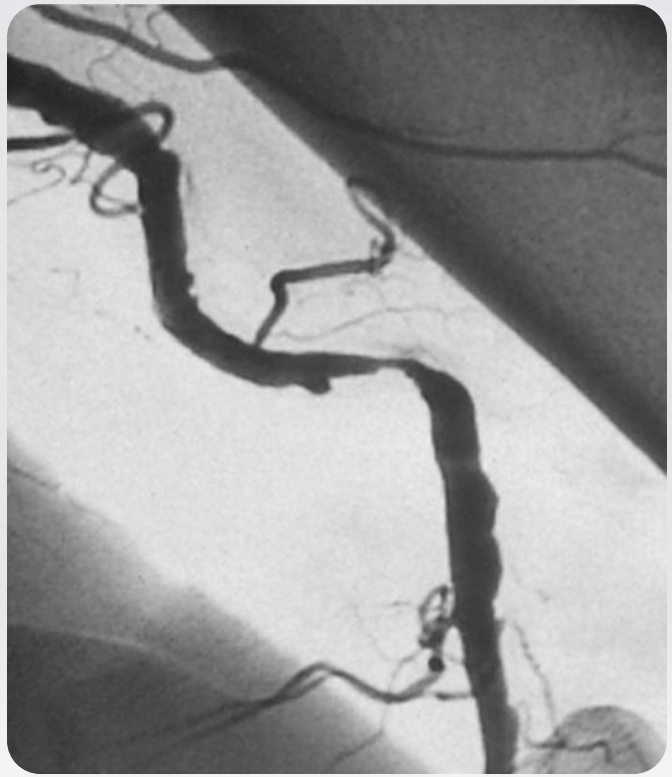
Extremely High Crush Resistancy

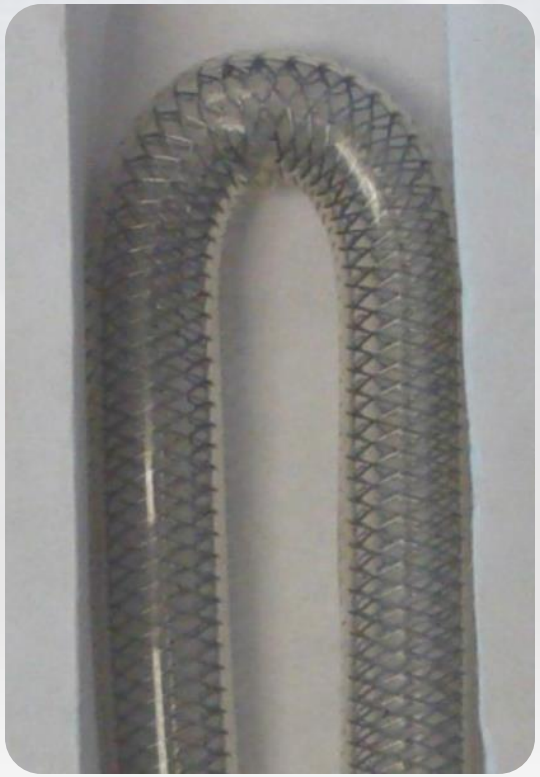
9 kg of compression resistance



VMI Supera (Abbott Vascular)

Extremely Flexibility & high kink resistancy





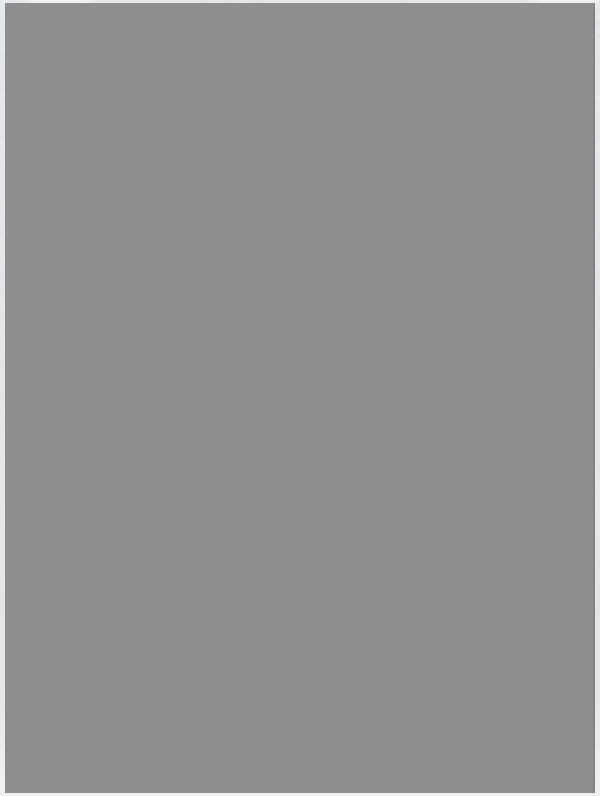
Supera 6-100

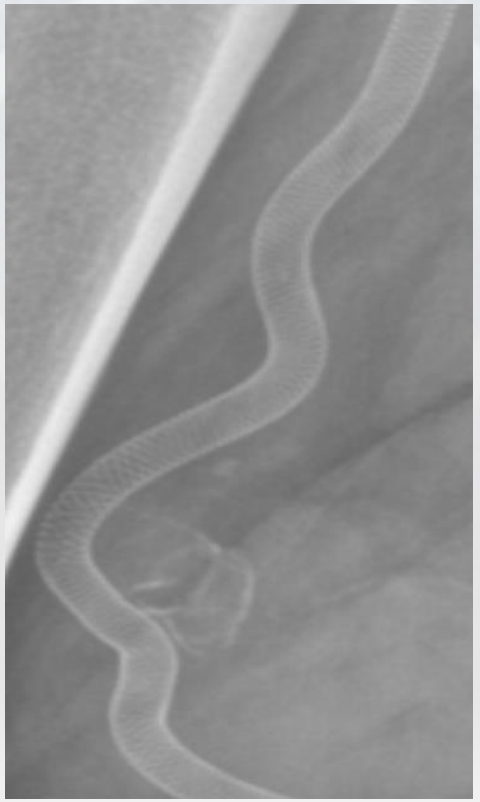
Zilver 6-100

Angio image courtesy of Dr. Gary Ansel

VMI Supera (Abbott Vascular)

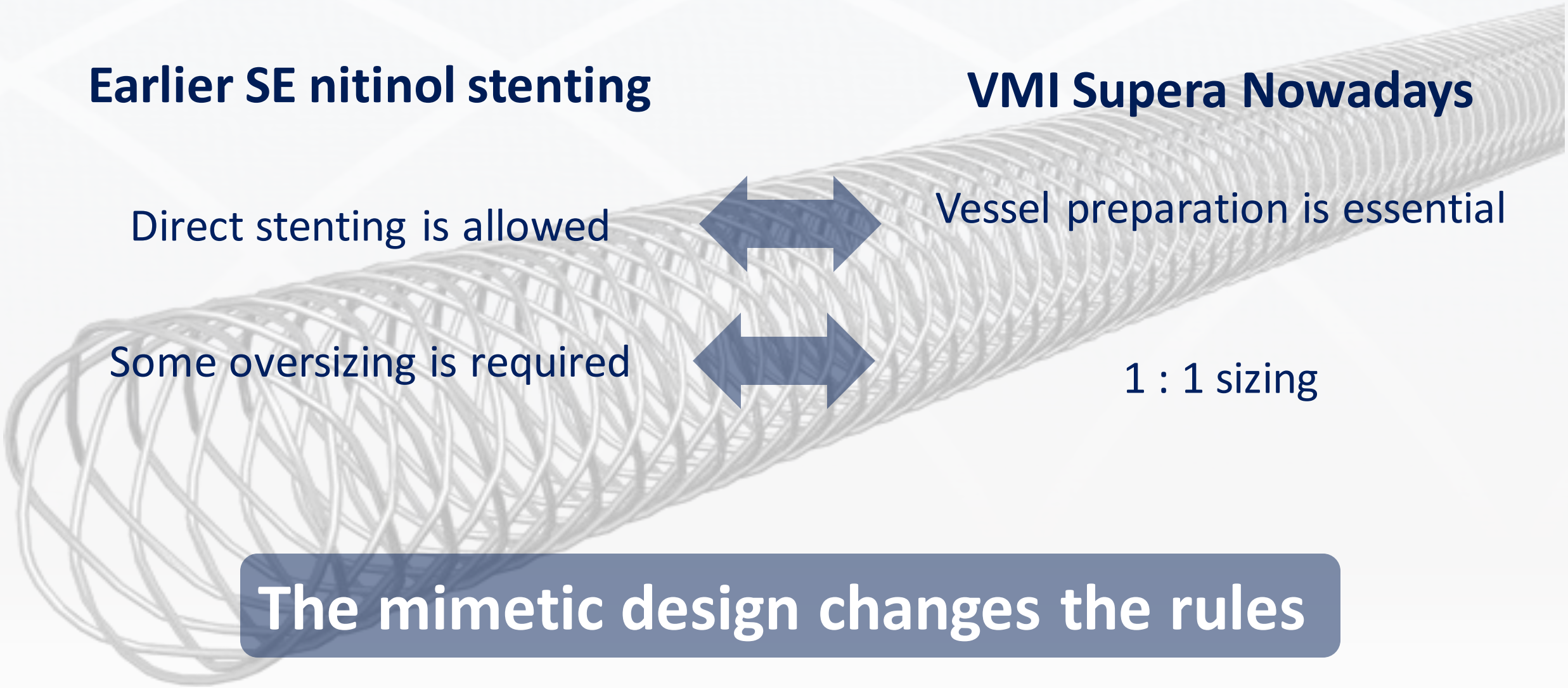
The VMI Supera supports natural vessel movement & maintains strength & flexibility despite vessel deformation.





1. Garcia, L., Rosenfield, K., et al. SUPERB Pivotal IDE Trial, 12-Month Results, TCT 2012.
2. Metzger, C., A Mechanical Problem Should Be Treated Mechanically. LINC 2013.
3. Scheinert, D., Why Conventional Stent Designs Fail in the SFA. VIVA 2013.

VMI Supera (Abbott Vascular)



Earlier SE nitinol stenting		VMI Supera Nowadays
Direct stenting is allowed	⇄	Vessel preparation is essential
Some oversizing is required	⇄	1 : 1 sizing

The mimetic design changes the rules

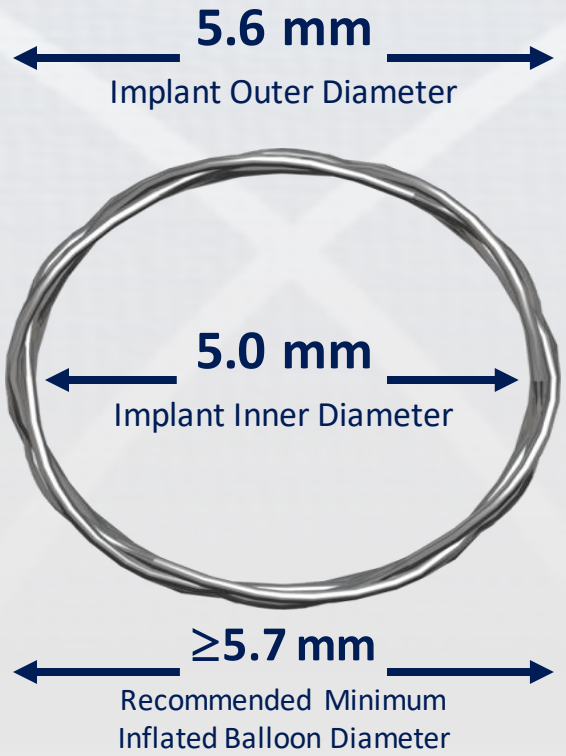
VMI Supera (Abbott Vascular)

- Vessel assessment : lesion length and RVD prox /dist
- Vessel preparation : prolonged PTA with 1 : 1 sized balloon over entire lesion length
- Re-PTA with shorter, non compliant balloon in refractory dense calcium areas
- Select the right SUPERA…

VMI Supera (Abbott Vascular)

- Correct SUPERA sizing…
- Correct RVD sizing

Implant Inner Diameter	Implant Outer Diameter	Minimum Inflated Balloon Diameter
4.0 mm	4.6 mm	≥4.7 mm
5.0 mm	5.6 mm	≥5.7 mm
6.0 mm	6.7 mm	≥6.8 mm
7.0 mm	7.7 mm	≥7.8 mm
8.0 mm	8.8 mm	≥8.9 mm



- Correct lesion length sizing (1cm margin)

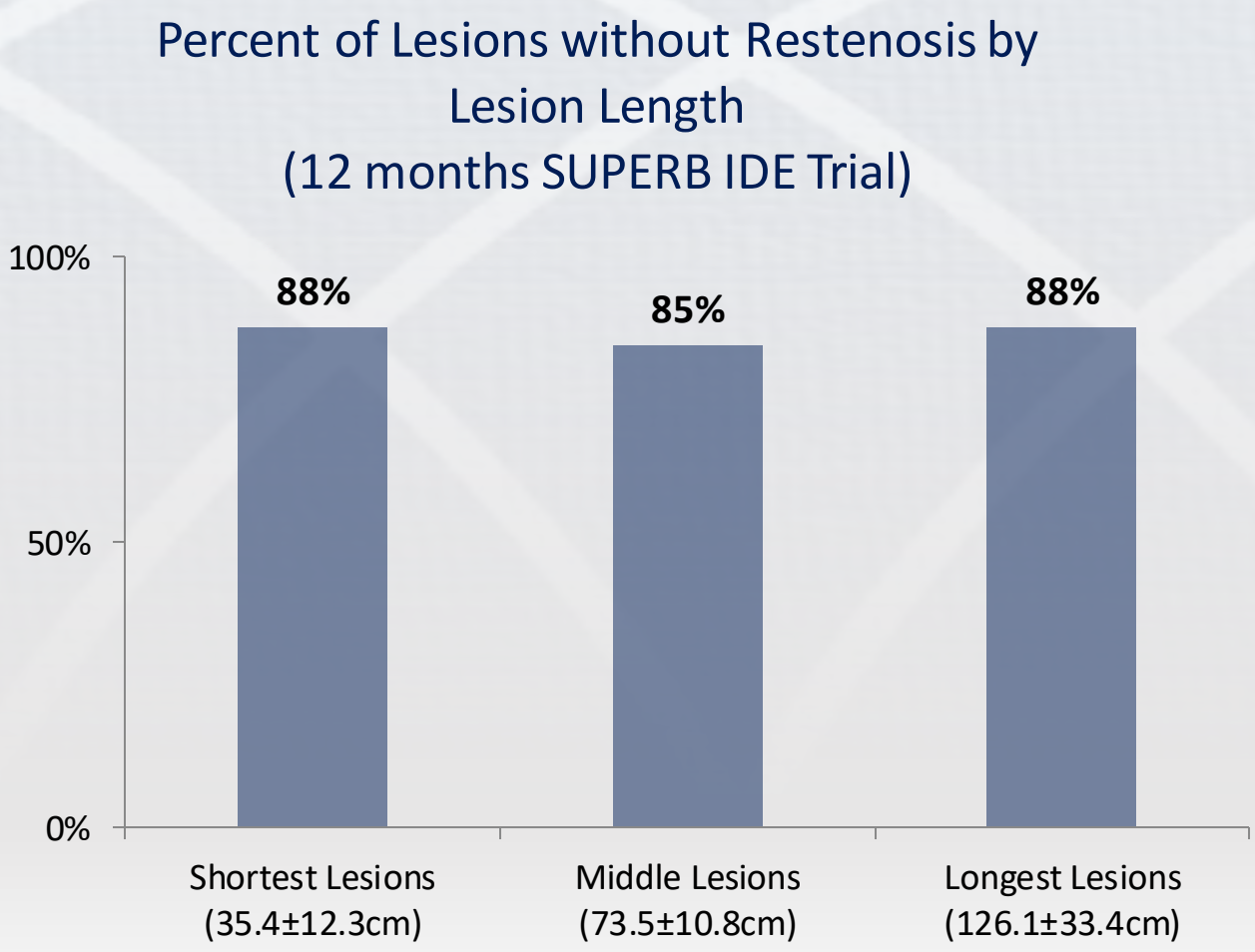
The post-dilated vessel should be at least the size of the outer stent diameter

VMI Supera (Abbott Vascular)

- Correct Supera Sizing

Reference vessel	4.0 mm	5.0 mm	6.0 mm
1:1 Supera implant	4.0 mm (4.6 mm OD)	5.0 mm (5.6 mm OD)	6.0 mm (6.7 mm OD)
Pre-dilatation balloon	4.0 or 5.0 mm	5.0 or 6.0 mm	6.0 or 7.0 mm
Pre-dilated vessel	≥4.7 mm	≥5.7 mm	≥6.8 mm

VMI Supera (Abbott Vascular)

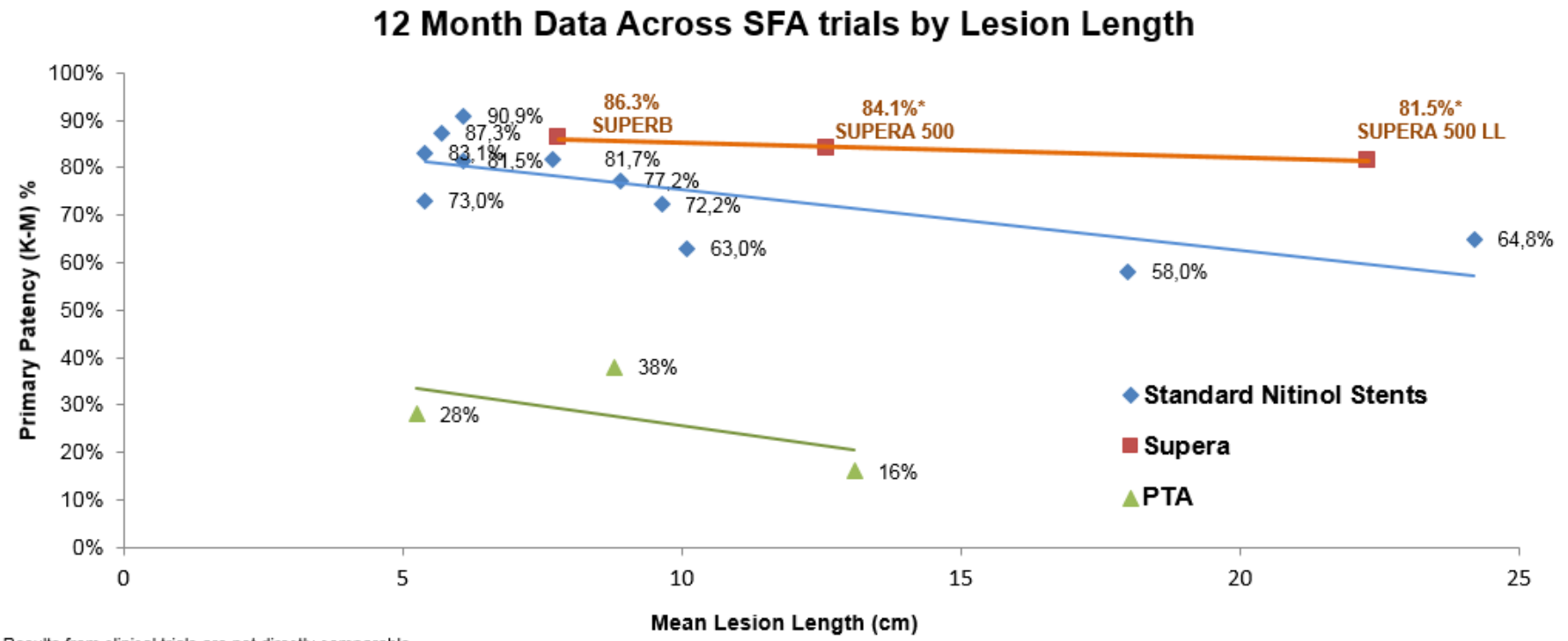


VMI Supera (Abbott Vascular)

	Mean lesion length (mm)	Number	1yr PPR (%) (duplex US)	2yr PPR (%) (duplex US)
SUPERA 500 LL	*223.4*	*172*	*81.5*	*67.9*
SUPERA CWZ The Netherlands	*240*	*159*	*74*	*na*
Tucsons' RESTORE Study	*184*	*147*	*88*	*na*

Scheinert et al. Presented @ LINC 2014, Leipzig, Germany
Molenaar et al. Presented @ Nederlandse Vaatdagen 2011, Noordwijkerhout, The Netherlands
Pacanowski et al. Presented @ LINC 2013, Leipzig, Germany

VMI Supera (Abbott Vascular)



Results from clinical trials are not directly comparable.
Information provided is for educational purposes only.

1. SUPERB: Garcia, L., Rosenfield, K., et al., SUPERB Pivotal IDE Trial, 12-Month Results, TCT 2012.
2. SUPERA 500: Scheinert, D. Results from the SUPERA 500 Registry. LINC 2013.
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4. COMPLETE SE: IFU, Complete SE.
5. Belgian ABSOLUTE: Schroe, H. Absolute BELGIAN study. CIRCE 2008.
6. ZILVER PTX: Dake, M.D., Ansel, G.M., Jaff, M.R., et al. Paclitaxel-Eluting Stents Show Superiority to Balloon Angioplasty and Bare Metal Stents in Femoropopliteal Disease: Twelve-Month Zilver PTX Randomized Study Results. Circ Cardiovasc Interv. 2011:4(5):495–504.
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8. STROLL: Ansel, G. STROLL Trial. LINC 2013.
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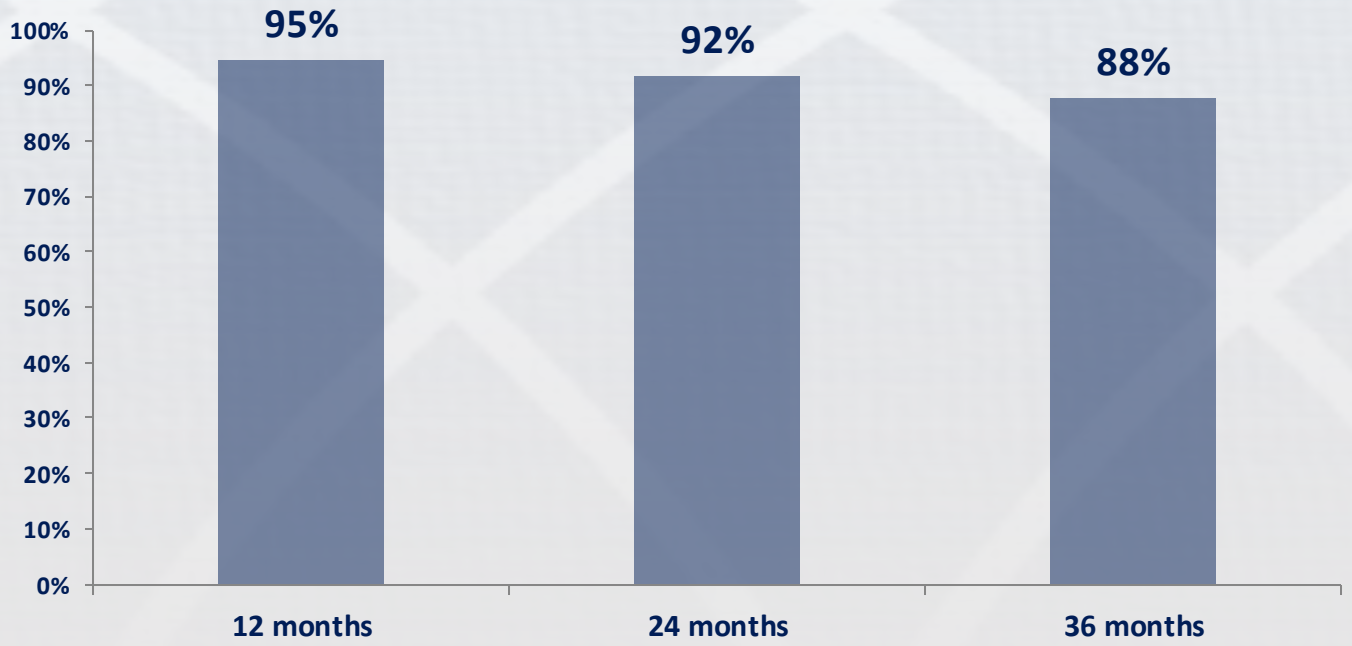
10. DURABILITY II: Everflex Instructions for Use.
11. DURABILITY I: Bosiers, M., Torsello, G., Gissler, H.M., et al. Nitinol Stent Implantation in Long Superficial Femoral Artery Lesions: 12-Month Results of the DURABILITY I Study. J Endovasc Ther. 2009;16(3):261–269.
12. DURABILITY 200: Bosiers, M. Durability 200 Study. LINC 2011.
13. Vienna ABSOLUTE: Schillinger, M., Sabeti, S., Loewe, C., et al. Balloon Angioplasty Versus Implantation of Nitinol Stents in the Superficial Femoral Artery. N Engl J Med. 2006;354(18):1879–1888.
14. VIBRANT (BMS): Ansel, G. One-year interim results: Gore VIBRANT clinical study. LINC 2010.
15. Rocha-Singh, K.J., Jaff, M.R., Crabtree, T.R., Bloch, D.A., Ansel, G.; VIVA Physicians, Inc. Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients with Symptomatic Peripheral Arterial Disease. Catheter Cardiovasc Interv. 2007;69(6):910–919.

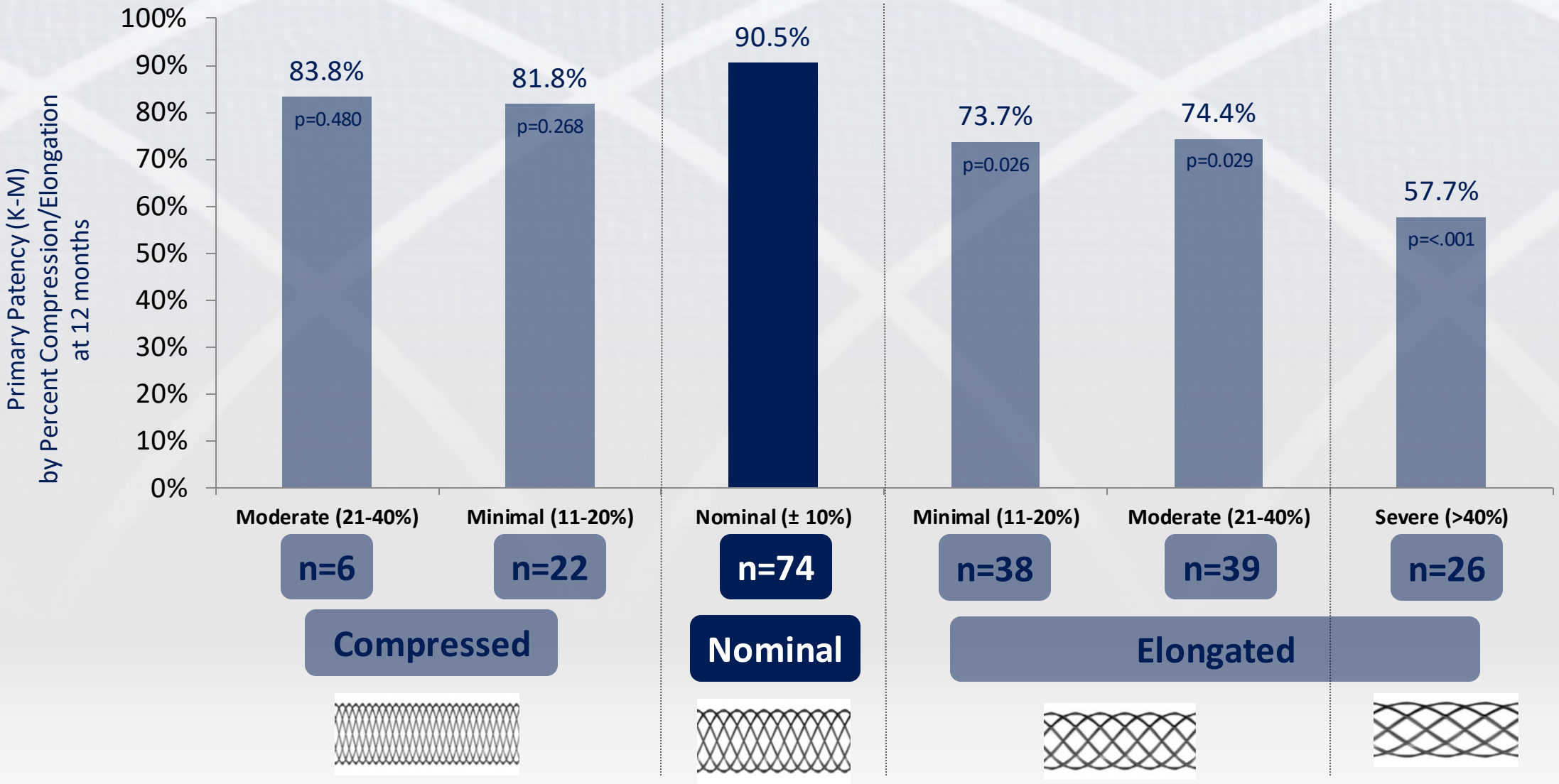
VMI Supera (Abbott Vascular)

Freedom from TLR % over time in severe calcium

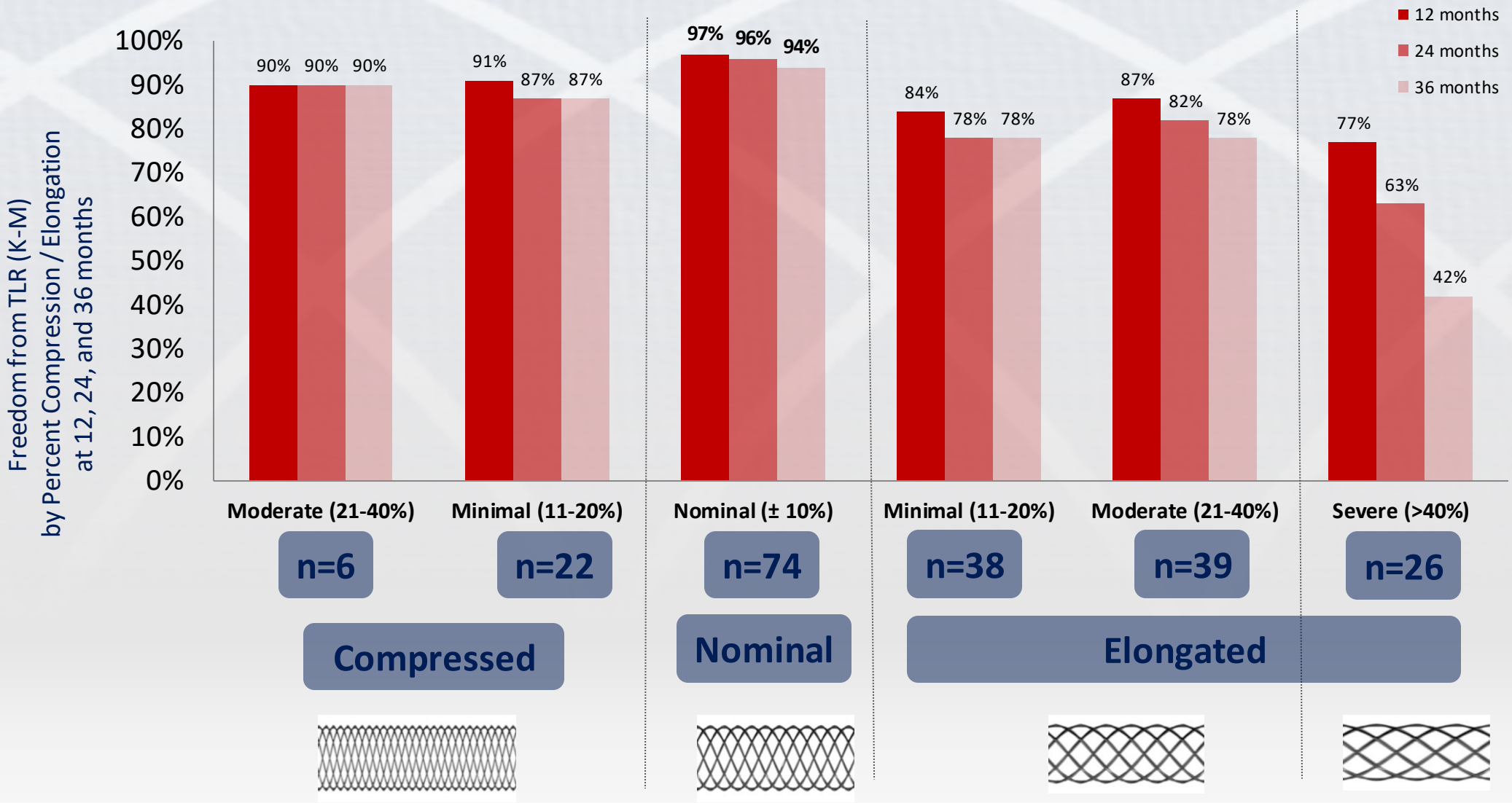


SUPERB Data - Severe Calcification	
% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%

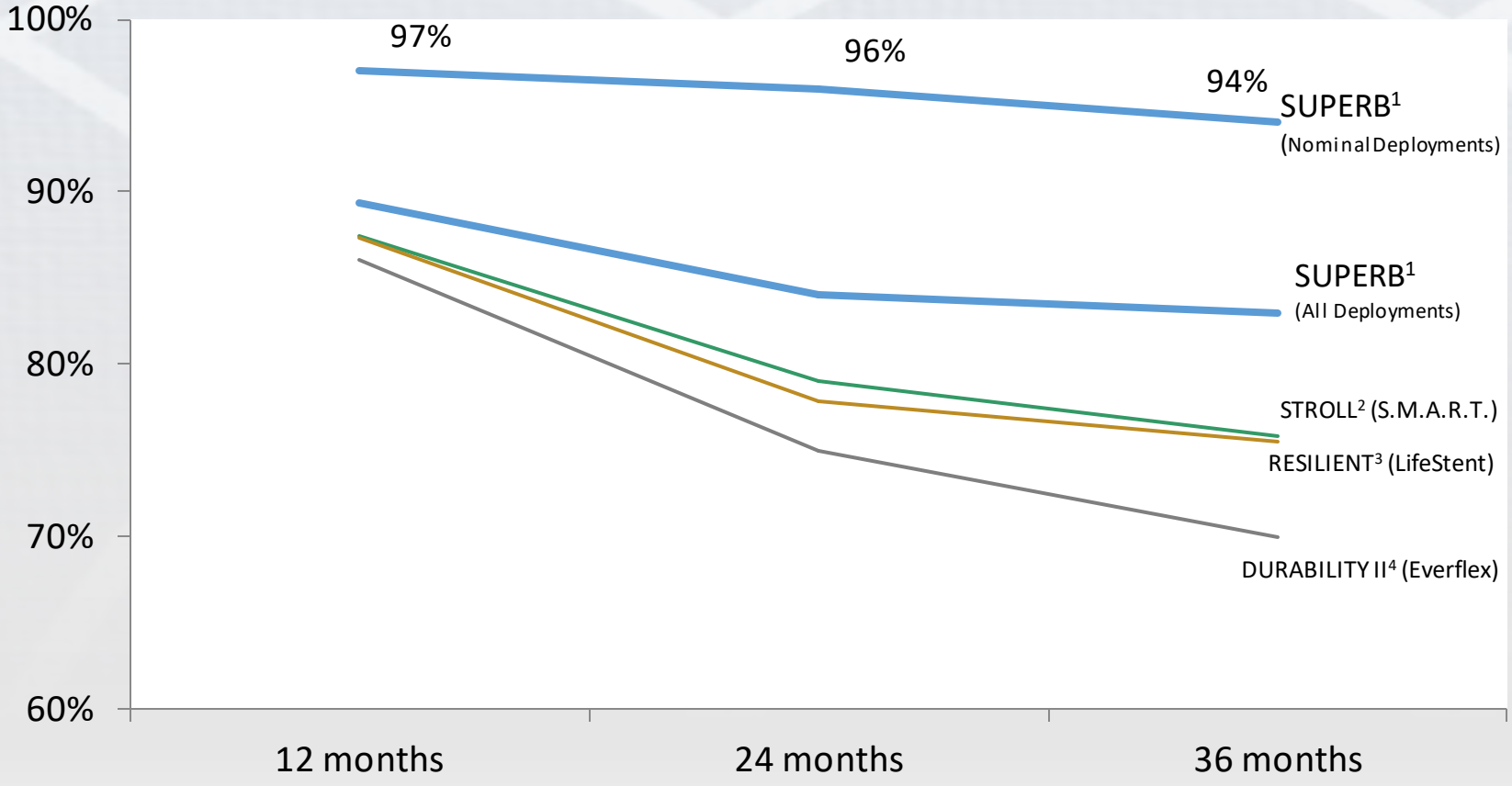
VMI Supera (Abbott Vascular)



VMI Supera (Abbott Vascular)



VMI Supera (Abbott Vascular)



1. *Clinical data on file at Abbott Vascular.*
2. *STROLL 1-year, G. Ansel, LINC 2013; 2-year, W. Gray ISET 2013. 3-year, M Jaff ISET 2014*
3. *Laird, J. Journal of Endovascular Therapy 2012;19:1–9*
4. *DURABILITY II, K Rocha-Singh, VIVA 13; M Razavi ISET 2014.*

VMI Supera (Abbott Vascular)

Baseline patient characteristics

	Supera (N=470)	BMS (N=432)	DEB (N=390)
Age, years	70.5 ± 10.2	67.5 ± 10.4	67.2 ± 10.6
Female, %	33	30	34
Rutherford stage, %	3.0 ± 0.9	3.3 ± 0.9	3.1 ± 0.9
Hypertension, %	95	92	95
Hyperlipidemia, %	57	57	74
Obesity (BMI>30 kg/m2), %	38	28	30
Diabetes, %	51	54	43
Current/former smoking, %	52	48	59
Coronary heart disease, %	56	44	35
Chronic kidney disease, %	26	12	12

Lesion and interventional characteristics

	Supera (N=470)	BMS (N=432)	DEB (N=390)
Lesion length, mm	**126 ± 82**	**148 ± 108**	**199 ± 116**
Instent restenosis, %	**13**	**16**	**27**
Run-off vessels	2.0±0.9	2.2±0.9	2.1±0.9
N of devices used	1.4±0.7	1.6±0.8	2.2±1.1
Device diameter, mm	5.3±0.5	6.5±0.5	5.1±0.6
Inflow intervention, %	11	3	8
Outflow intervention, %	14	8	14
Retrograd access, %	4	0.5	9
Residual stenosis ≥30%, %	0.5	1	9
ABI, post intervention	0.9±0.1	0.9±0.1	0.9±0.2

With the courtesy of Dr Steinman, @LINC 2015, Leipzig, Germany

VMI Supera (Abbott Vascular)

DCB – BMS - Supera

- To reduce selection bias - > Calculation of propensity scores (clinical and lesion characteristics)
- 1:1 match (nearest neighbour): forming matched data sets for each comparison who share a similar value of the propensity score
- In order to achieve a similar distribution of baseline covariates between the compared groups

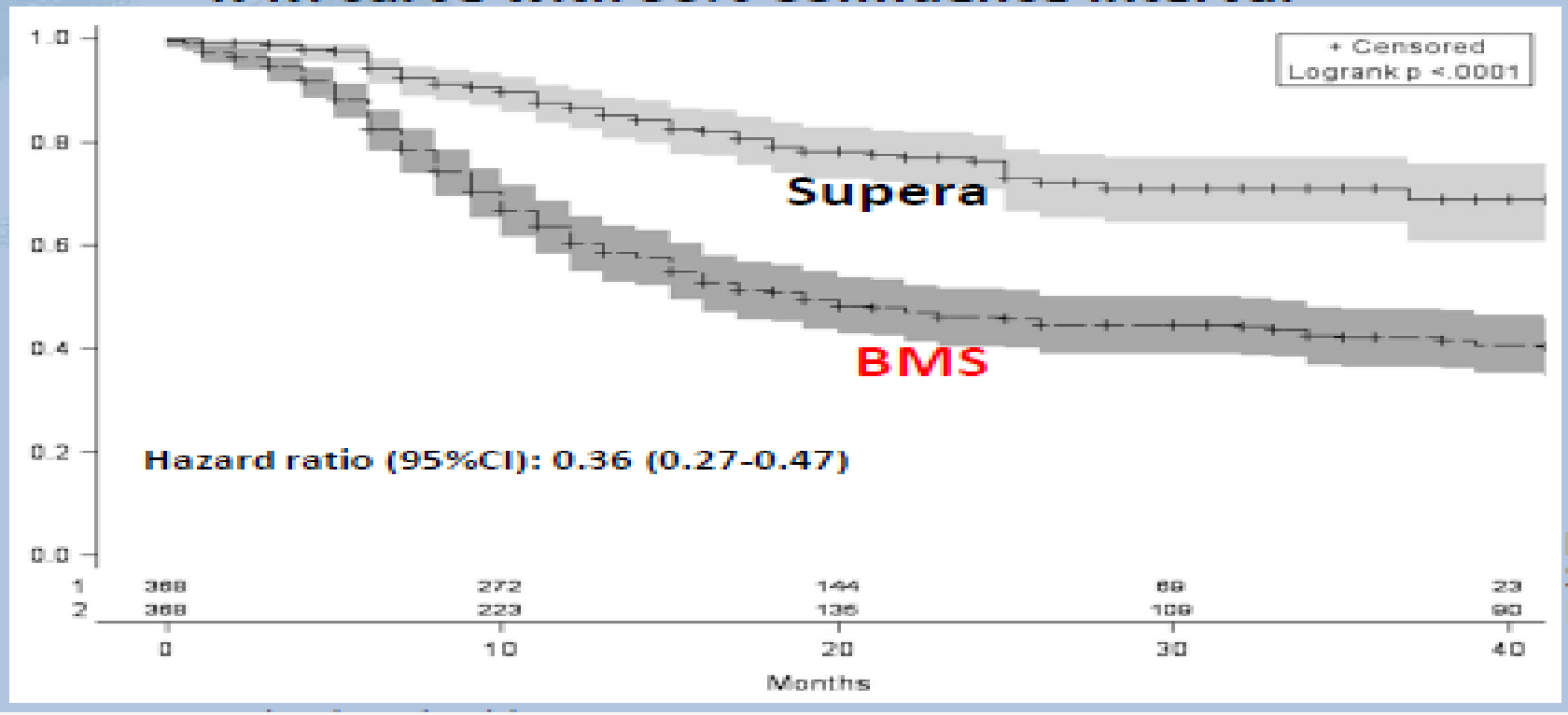
With the courtesy of Sabine Steiner, MD @LINC 2015, Leipzig, Germany

VMI Supera (Abbott Vascular)

Supera - BMS

Matched Cohort:	Supera	BMS	P-Value
Lesion length, mm	130 ± 83	139 ± 100	0.2
Instent restenosis, %	16	16	0.9

K-M curve with 95% Confidence Interval

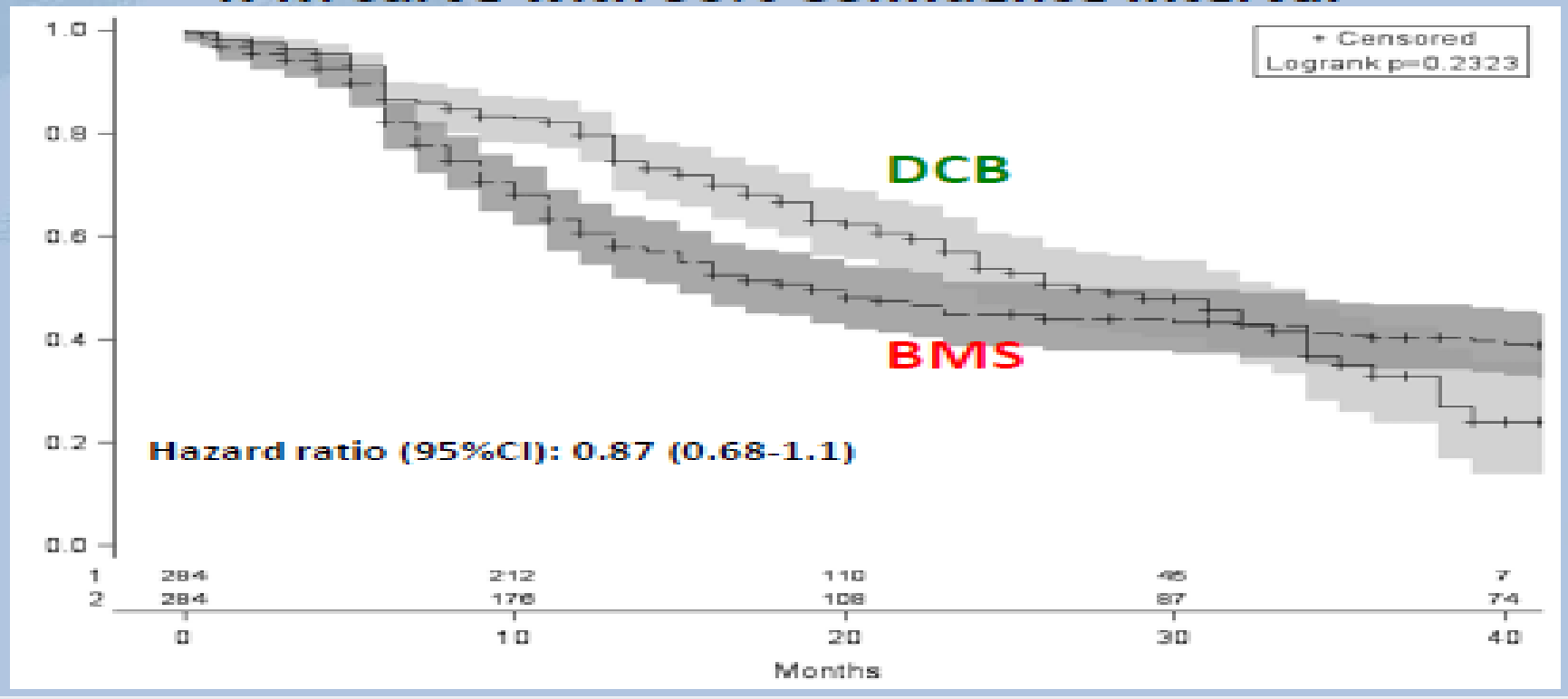


VMI Supera (Abbott Vascular)

DCB - BMS

Matched Cohort:	DCB	BMS	P-Value
Lesion length, mm	171 ± 108	159 ± 114	0.2
Instent restenosis, %	18	19	0.8

K-M curve with 95% Confidence Interval



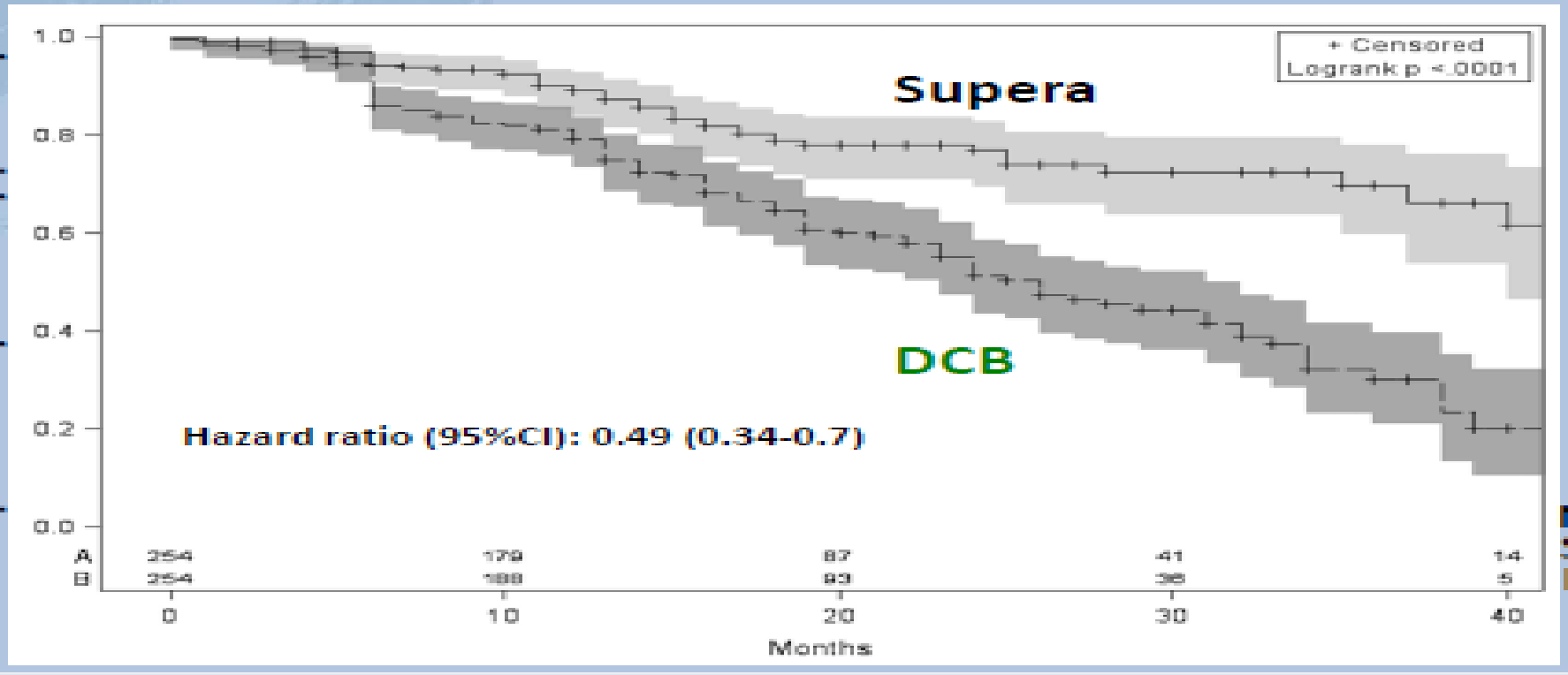
With the courtesy of Sabine Steiner, MD @LINC 2015, Leipzig, Germany

VMI Supera (Abbott Vascular)

Supera -DCB

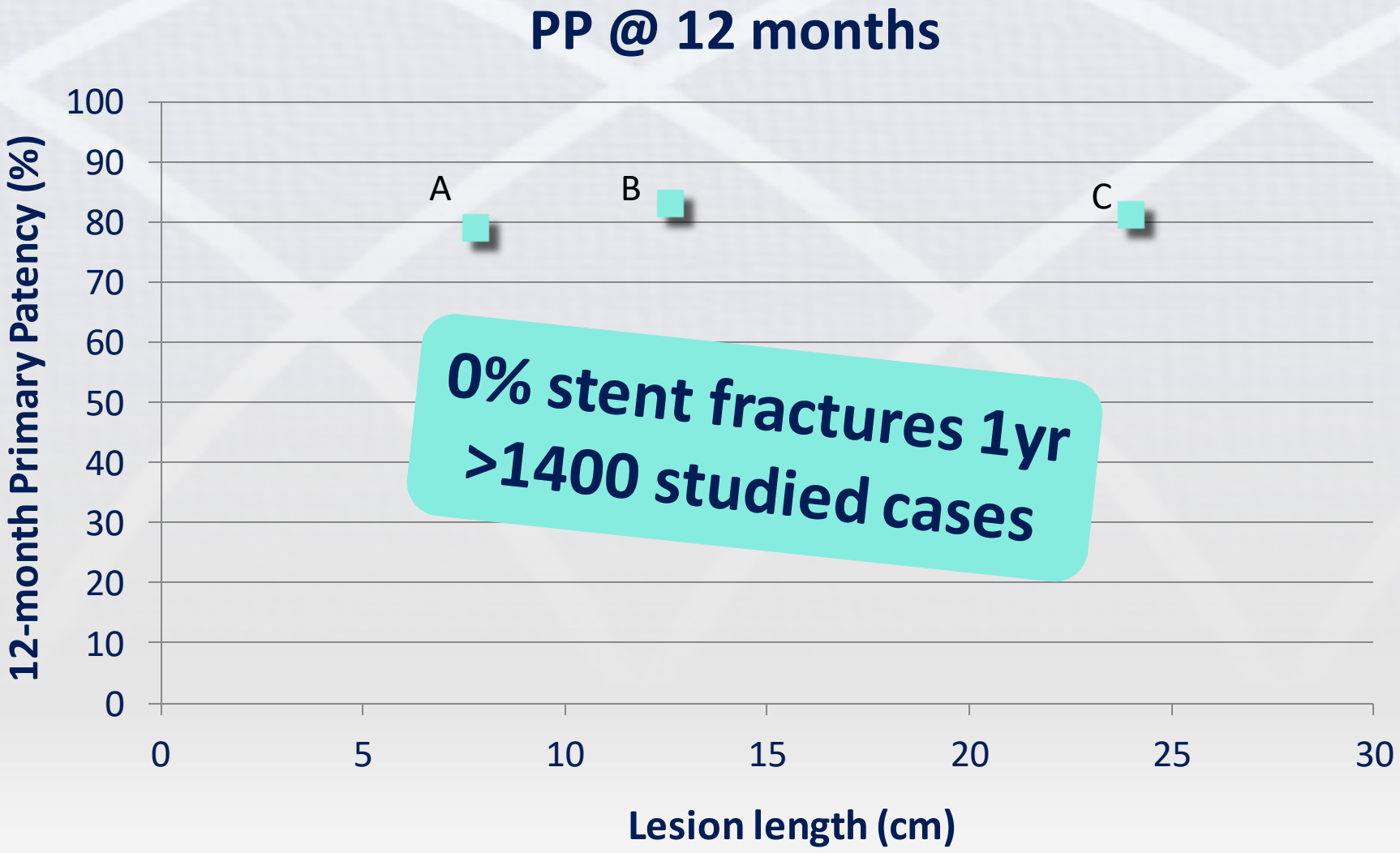
Matched Cohort:	Supera	DCB	P-Value
Lesion length, mm	143 ± 92	157 ± 102	0.09
Instent restenosis, %	16	17	0.6

K-M curve with 95% Confidence Interval



With the courtesy of Sabine Steiner, MD @LINC 2015, Leipzig, Germany

Results with VMI in the SFA



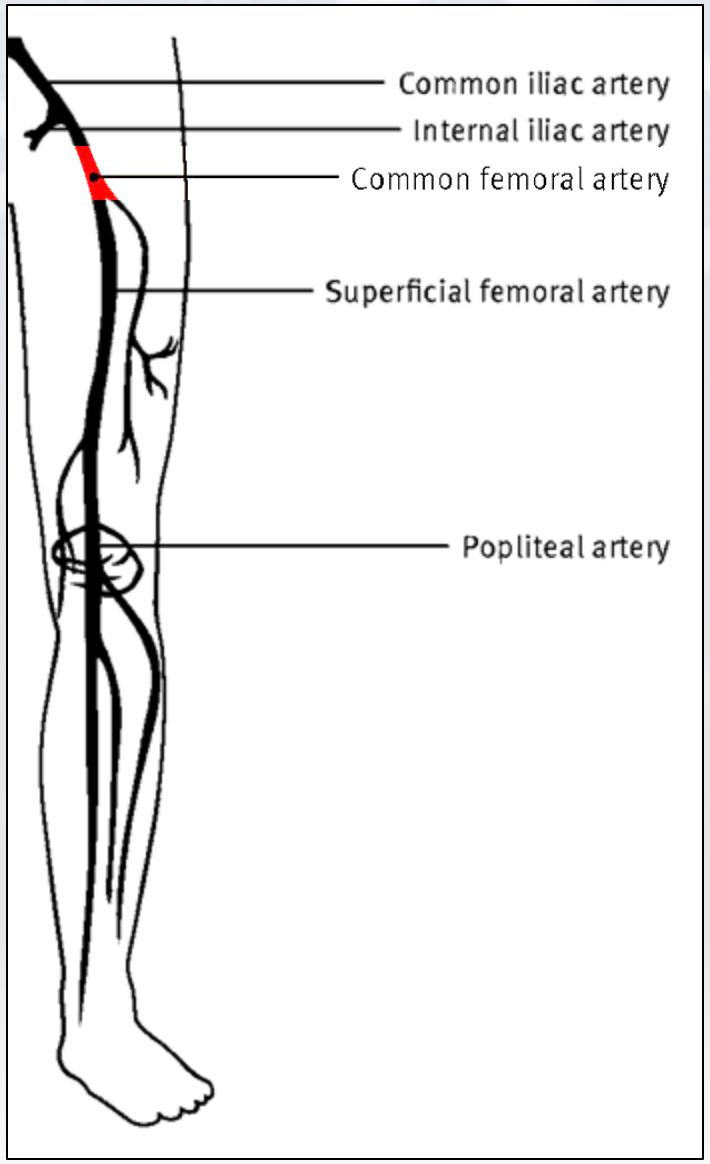
VMI

A. Superb registry
B. Supera 500
C. Supera 500 LL

Limitations of VMI in the SFA

- Device limitations
- More pronounced learning curve
- Permanent implant

Common Femoral Artery



1. Femoropopliteal Artery
    - Plain Old Balloon Angioplasty
    - Bare Metal Stenting
    - Drug Eluting Stenting
    - Drug Coated Balloon Angioplasty
    - Vascular Mimetic Implant

2. Common Femoral Artery

CFE = Golden standard…

Ballotta et al. (Surgery 2010;147:268-274)

- 8 yr single center, prospective study, 117 pts
- PPR @ 1,3,5 & 7 years : 100%, 99%, 96%, 96%
- APP: 100% - LSR : 100%

Kang et al. (J Vasc Surg 2008;48:872-7)

- 5 yr single center, prospective study, 58 pts
- PPR @ 1 & 5 years : 93% , 91%
- APP: 100%

Kechagias et al. (World J Surg 2008;32:51-54)

- 15 yr single center, prospective study, 111 pts
- PPR: na-LSR @ 5, 10, 15 yrs : 93.7% , 93.7% ; 85.2%
- F-TLR @ 5, 10, 15 yrs : 68%, 50.6% , 42.5%

But it has a Dark Side

Ballotta et al. (Surgery 2010;147:268-274)
- 6.6% minor complication rate
- Mainly lymph leaks

Kang et al. (J Vasc Surg 2008;48:872-7)
- 13.8% complication rate
- 5% required reintervention

Kechagias et al. (World J Surg 2008;32:51-54)
- 17.1% wound infection rate
- 9% hematomas

But it has a Dark Side

Derksen et al. (Vasc End Surg 2009;43:69-75)

140 pts, retrospective

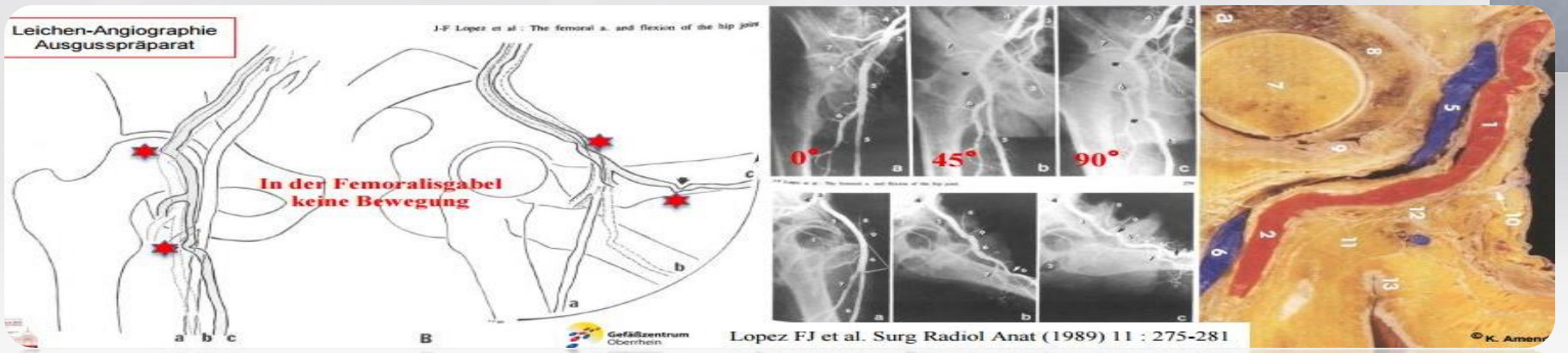
- 14% wound infection rate
  - 9% superficial infections
  - 5% deep infections
- 2 cases involvement of patch

Cardon et al. (Ann Chir 2001;126(8):777-82)

- 18% minor complication rate
- 3.6% major complication rate

Is endovascular treatment an alternative?

- Bulky, eccentric, heavily calcified plaques
- Frequently femoral bifurcation involvement
- Location prone to crush
- (surgical/endovascular) access area
- Relatively fixed segment



Is endovascular treatment an alternative?

Silva et al. (Cath Cardiovasc Interv 2004;62:230-3)

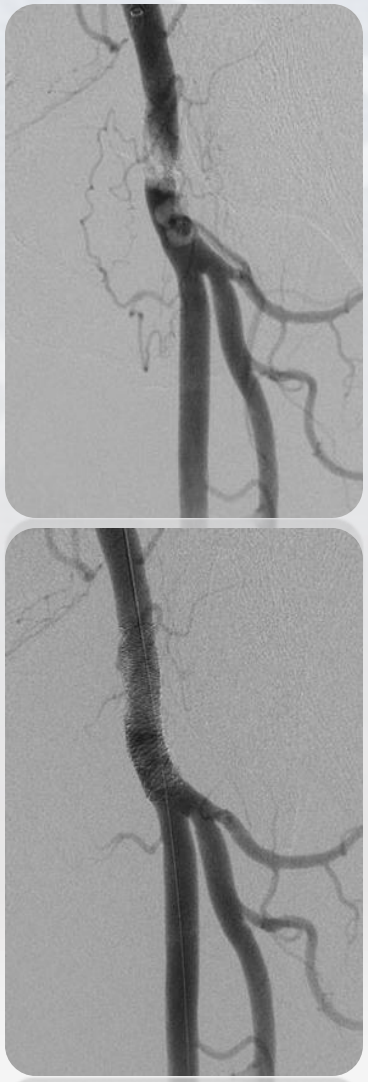
- Single center, retrospective study, 21 CFA POBA's
- Procedural success: 90%
- Clinical improvement (>1 RB category) 89%

Stricker et al. (J Endovasc Ther 2004;11:281-6)

- Single center, retrospective study, 33 CFA POBA + stent
- Procedural success: 100%
- PPR @ 3 yrs: 83%

Azéma et al. (Eur J Vasc EV Surg 2011;41:787-793)

- Single center, prospective study, 36 CFA stenting
- Procedural success: 100%
- PPR @ 1 yr: 80% - f-TLR @ 1 yr: 85% - 1 stent# (EIA!)



Is endovasuclar treatment an alternative?

Bonvini et al. (J Am Coll Cardiol 2011;58:792-8)

- Single center, retrospective study, 360 CFA POBA's
- Mainly POBA (98,6%) – Stents (36,9%) – Atherectomu (6,9%)
- Technical success rate: 92,8%
- PPR @ 1 yr: 72,4% - f-TLR @ 1yr: 88,1%
- Stenting independent predictor for less restenosis/TLR

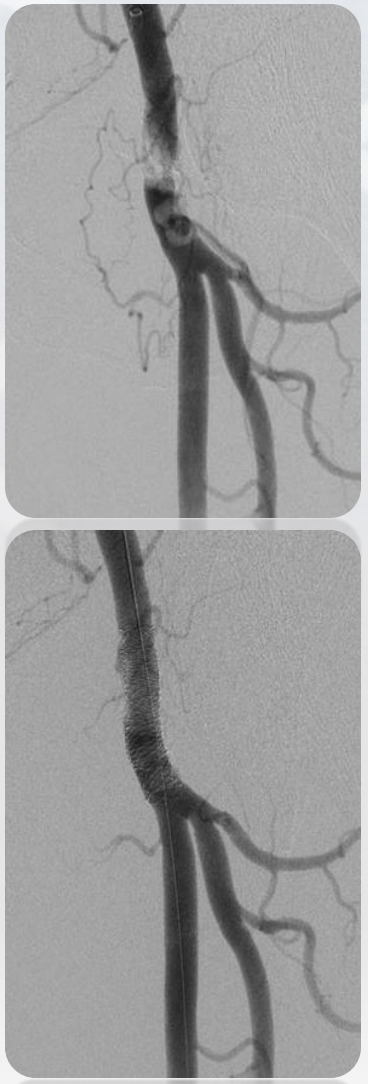
A LOT OF REMAINING QUESTIONS

Long term follow-up?

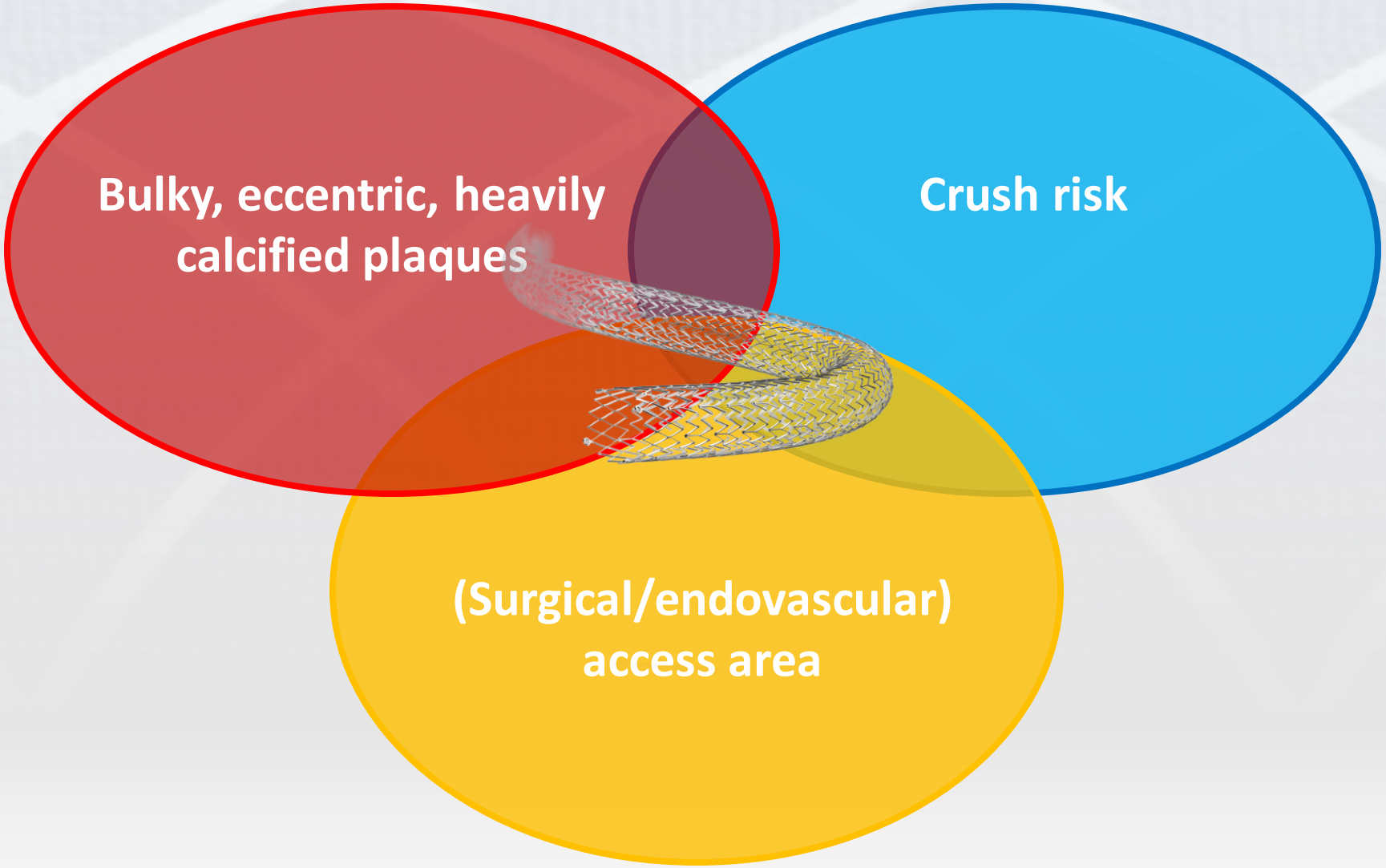
No standardized imaging FU

No Kaplan-Meier curve outcome analysis

MODERN ENDOVASCULAR DEVICES



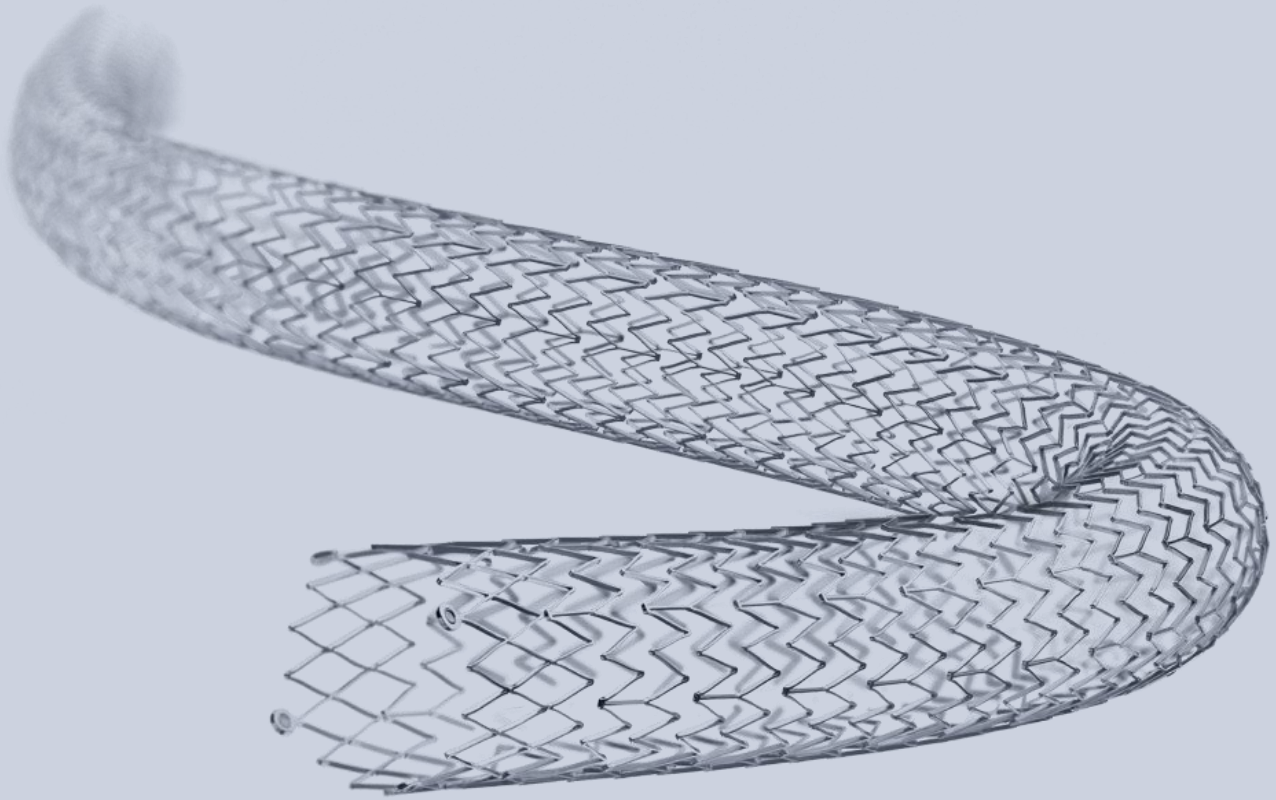
Is endovascular treatment an alternative?



CFA	Surgery	VMI Supera
Ca^{++}	✓	✓
Crush	✓	✓
Fixed	✓	✓
Access	✓	✓
Anatomy-Morbidity	✗	✓
Durability	✓	?

The Supera VMI (Abbott Vascular)

VMI CFA study



Supera VMI

100 subjects

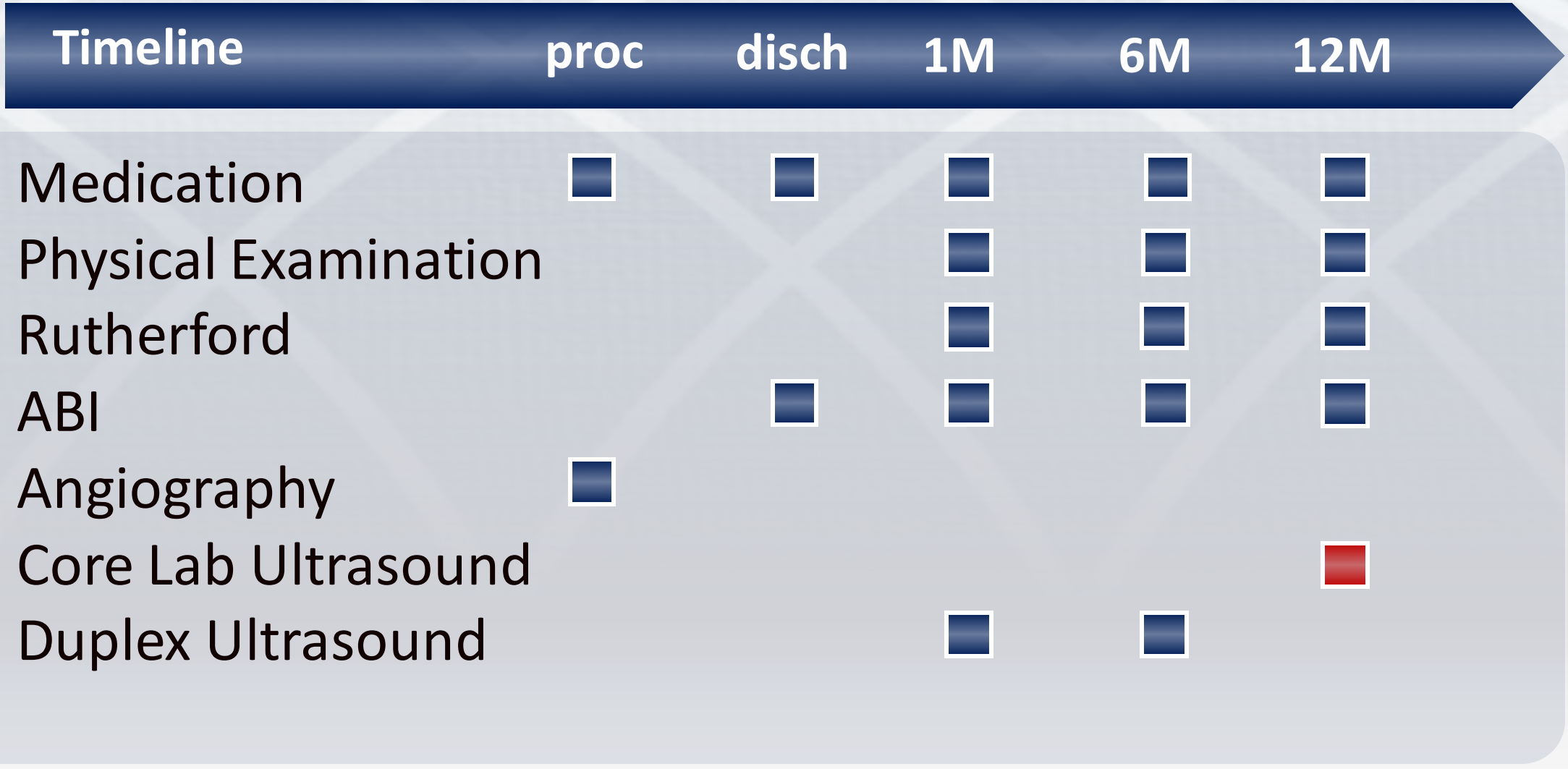
Primary Endpoint:

Primary patency at 12 months, defined as freedom from >50% restenosis as indicated by an independent core-lab verified duplex ultrasound PSVR <2.5 in the target vessel with no re-intervention within 12 months

Rutherford Classification 2,3,4

De novo lesions in the CFA

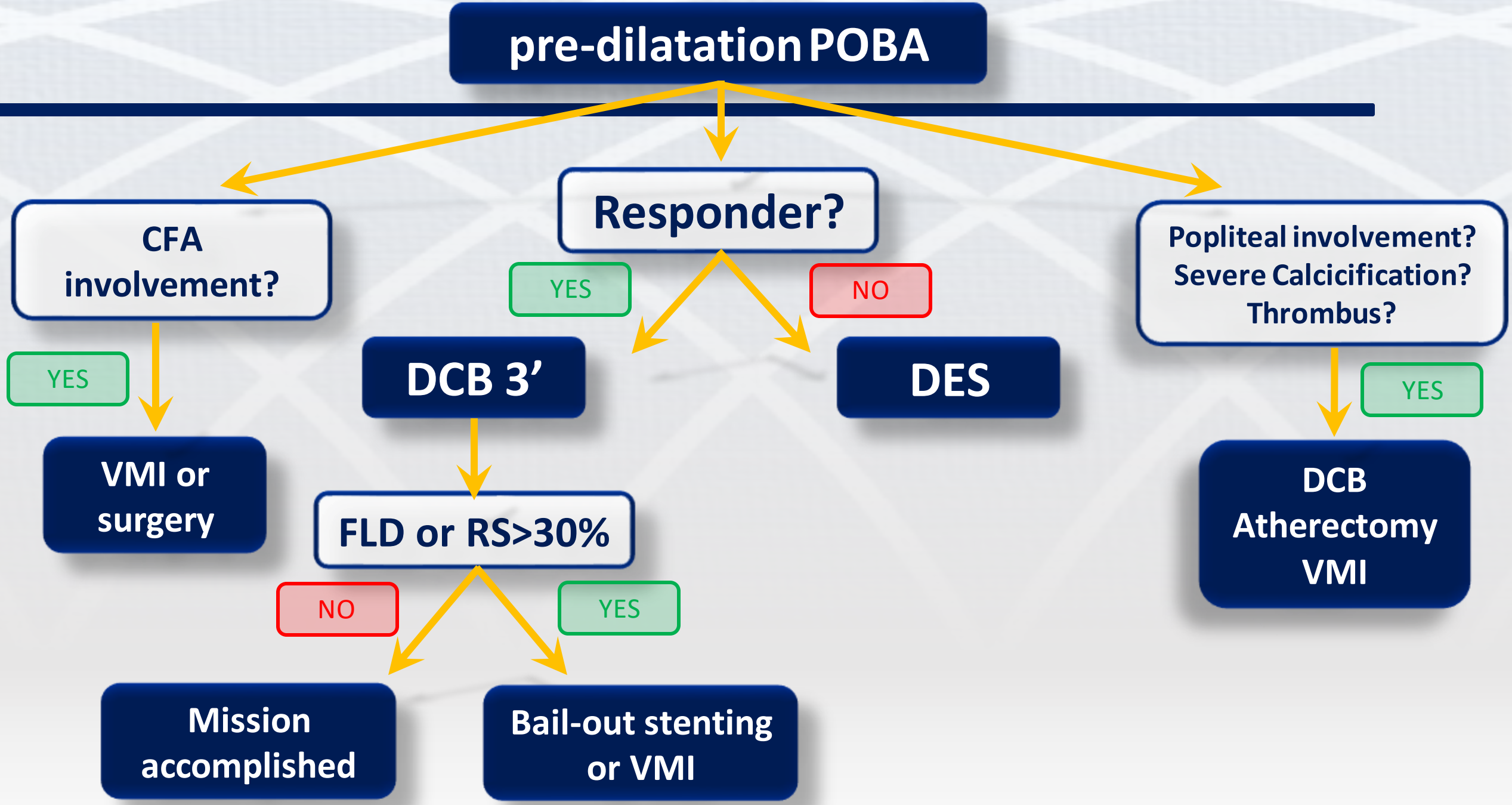
Timetable


Timeline
proc
disch
1M
6M
12M
Medication
Physical Examination
Rutherford
ABI
Angiography
Core Lab Ultrasound
Duplex Ultrasound

Enrollment

VMI-CFA

83 out of 100 patients are enrolled


pre-dilatation POBA
CFA involvement?
YES
VMI or surgery
Responder?
YES
NO
DCB 3’
DES
FLD or RS>30%
NO
YES
Mission accomplished
Bail-out stenting or VMI
Popliteal involvement? Severe Calcification? Thrombus?
YES
DCB Atherectomy VMI

Conclusion

- Initial DCB patency-results in long lesions seems excellent
- In case of scaffold-need VMI (esspecially for Ca & politeal) or BMS are the candidates of 2016
- DES & Covered Stents show high safety & efficacy but struggle with health-economics and initial "no metallic implant" concepts
- Although importantly shrinking, there still remain some indications for bypass surgery